

राष्ट्रीय क्षयरोग संस्थान
NATIONAL TUBERCULOSIS INSTITUTE

एन. टी. आई. अध्ययनों का सारांश
SUMMARIES OF NTI STUDIES

VOLUME - 2
(1995 - 2005)



भारत सरकार

राष्ट्रीय क्षयरोग संस्थान

(स्वास्थ्य सेवा महानिदेशालय)

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सम्पादन

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प्रक्कथन

विकासशील विश्व में क्षय रोग से, नीरवता से ही सही, लाखों की संख्या में लोग मर रहे हैं । करीब बीस लाख नए क्षय रोगियों के साथ, जिनमें से आधे तीव्र संक्रामक हैं, विश्व में अधिक संख्यक क्षय रोगियों को पालने की संदिग्ध ख्याति भारत की है । तथापि, हाल ही में प्रवर्तित संशोधित राष्ट्रीय क्षय रोग नियंत्रण कार्यक्रम एक आशा की किरण पेश करता है एवं कार्यक्रम का प्रोत्साहक निष्पादन इसका एक सबूत है । सभी राष्ट्रीय जन स्वास्थ्य कार्यक्रमों के संपोषित एवं प्रभावी कार्यान्वयन के लिए प्रचालन शोध की आवश्यकता होती है तथा क्षय रोग के संदर्भ में इस पहलू पर और अधिक जोर देने की आवश्यकता नहीं है ।

एन.टी.आई, बेंगलूर के महत्वपूर्ण अध्यादेशों में एक है, क्षय रोग नियंत्रण कार्यक्रम में सार्थक निवेश उपलब्ध कराने के लिए शोध अध्ययन सम्पन्न करें । मरक विज्ञान तथा प्रचालन शोध से लेकर आई ई सी तथा समाजविज्ञान तक के विस्तृत क्षेत्रों में एन टी आई द्वारा अनेक उल्लेखनीय अध्ययन तथा कुछ अंतर्राष्ट्रीय अध्ययन सम्पन्न किए गए हैं । एन टी आई अध्ययनों के सारयुक्त यह खण्ड, 1995-2004 के बीच प्रकाशित विश्लेषणात्मक अध्ययन, समीक्षा एवं समकालीन लेखों के पूर्ववर्ती संकलन का उत्तरांश है । तत्कालीन राष्ट्रीय क्षय रोग कार्यक्रम पर आधारित कुछ लेख वर्तमान संदर्भ में अप्रासंगिक लग सकते हैं, किंतु पाठक के सामने क्षय रोग नियंत्रण की नवीनतम युक्तियों की व्युत्पत्ति की बुनियाद को उजागर करते हैं। इस दस्तावेज के साथ लेखक एवं विषय सूचियाँ दी गई हैं, ताकि पाठक अपनी रुचि के निर्दिष्ट विषयों पर दृष्टिपात कर सके । उक्त लेख अनुसंधायकों, क्षय रोग कार्यकर्ताओं, विद्वानों, शिक्षकों एवं विद्यार्थियों के लिए सूचनात्मक व उपयोगी होंगे । ज्ञान की तलाश अनंत है, एवं आशा की जाती है कि यह साहित्य क्षय रोग के अनछुए क्षेत्रों में शोध के लिए प्रेरणा प्रदान करेगा ।

डॉ प्रहलाद कुमार
निदेशक

PREFACE

Tuberculosis continues to kill millions in the developing world, albeit silently. Accounting for about two million new TB cases with about half of them being highly infectious, India has the dubious distinction of harbouring the largest number of TB cases in the world. However, the Revised National Tuberculosis Control Programme launched in the recent past provides a vista of hope and encouraging the performance of the programme is a testimony to this. All national public health programmes require operation research for their sustained and effective implementation and in the case of TB this facet cannot be over-emphasized.

One of the important mandates of N^{TI}, Bangalore is to conduct research studies to provide meaningful inputs into the TB control programme. Several noteworthy studies, a few even internationally acclaimed have been undertaken by N^{TI} in a vast spectra of fields ranging from epidemiology and operation research to IEC and sociology. This volume of Summaries of N^{TI} studies is sequel to an earlier compilation and comprises of analytical studies, reviews and conceptual articles published between 1995-2005. Some of the articles on the erstwhile National Tuberculosis Programme may sound out of sync in the current context but would give the reader an insight into the foundations for the evolvement of newer strategies for TB Control. This document is supplemented with the author and subject index to help the reader to navigate through specific topics of interest. The articles are bound to be informative and useful to researchers, TB workers, academicians, teachers and students. The quest for knowledge being unending, the literature is also expected to provide impetus for research in the unexplored areas of tuberculosis.

*Dr Prahlad Kumar
Director*

प्रकाशन के बारे में

यह दस्तावेज एन टी आई अध्ययनों के सार - खण्ड I , जिसके अंतर्गत 1960 से 1997 तक के लेखों को वर्ष 1997 में प्रकाशित किया गया था, का अगला खण्ड है । इस दस्तावेज का उद्देश्य है, राष्ट्रीय क्षय रोग संस्थान द्वारा संचालित पूरे समुदाय की शोध से प्राप्त हुए क्षय रोग संबंधी विभिन्न पहलुओं के ज्ञान से अनुसंधायकों, कार्यक्रम कार्यकर्ताओं, नीति निर्णायकों, छात्रों, विद्वानों एवं अन्य पाठकों को अवगत कराना । इस अवधि के दौरान संपन्न अध्ययनों से निसृत भूमिका, उद्देश्य, परिणाम एवं निष्कर्ष को संक्षेप में पेश करना इस दस्तावेज का उद्देश्य है । साथ ही, अनेक वैचारिक समीक्षाएँ एवं मूल्यांकन लेखों को भी इसमें शामिल किया गया है ।

इस दस्तावेज में, अठहत्तर (78) वैज्ञानिक प्रकाशित लेखों के सार विषयवार एवं तदनंतर कालक्रमानुसार मुख्य शब्दों (की वर्ड्स) के साथ व्यवस्थित हैं । प्रत्येक सार के लिए विनिर्दिष्ट मुख्य शब्दों के उपयोग से विषय सूची बनाई गई है तथा लेखक सूची में सभी लेखक एवं कॉर्पोरेट निकाय शामिल हैं । इससे प्रयोक्ता को विशेष रुचि के विषय को आसानी से निकालने में मदद मिलेगी ।

डॉ वी.के. चड्ढा

वरिष्ठ जनपदिक रोग विज्ञानी

About the publication

This document is in continuation of 'Summaries of N'TI studies volume I which covered the papers published from 1960 to 1997 published in the year 1997. The objective of this document is to update the knowledge on various aspects of TB evolved by the community wide research conducted by the N'TI, Bangalore to the researchers, programme workers, policy makers, students, academicians and other readers. The purpose of this document is to present in brief the background, objectives, results and conclusion derived from the studies conducted during this period. Besides, many conceptual review and evaluation papers have also been included.

In this document, the summaries of 78 scientific published papers are arranged topic wise and subsequently chronologically accompanied by key words. Subject index is derived by using the key words assigned to each summary and author index includes all authors and corporate body. This will help the users to retrieve the topic of specific interest easily.

*Dr VK Chadha
Sr Epidemiologist*

आभारेक्ति

सारों के संकलन में संस्थान के सभी संकाय सदस्यों द्वारा प्रदान की गई सहायता को हम साभार मानते हैं । हम राष्ट्रीय क्षय रोग संस्थान, बेंगलूर के पूर्व एवं वर्तमान स्टाफ के योगदानों के प्रति भी आभार व्यक्त करना चाहते हैं, जिनकी निष्ठापूर्वक कोशिशों के बिना ये अध्ययन पूर्ण नहीं होते ।

Acknowledgement

We acknowledge the assistance rendered by all the faculty members of the institute in compiling the summaries. We also wish to acknowledge the contributions made by the past and present staff of the National Tuberculosis Institute, Bangalore without whose dedicated effort the studies would not have been completed.

LIST OF ABBREVIATIONS

01	AFB	Acid Fast Bacilli
02	ARTI	Annual Risk of Tuberculous Infection
03	AW	Anganawadi Worker
04	BMP	Bangalore Mahanagara Palike
05	BCG	Bacillus Calmette Guerin
06	CAT	Category
07	CI	Confidence interval
08	CO ₂	Carbon dioxide
09	CTD	Central TB Division
10	DALYs	Disability Adjusted Life Years
11	DGHS	Directorate General of Health Services
12	DNA	Deoxyribo-nucleic acid
13	DOTS	Directly Observed Treatment Short Course
14	DOT	Directly Observed Treatment
15	DRS	Drug Resistance Surveillance
16	DTC	District Tuberculosis Center
17	DTP	District Tuberculosis Programme
18	ELISA	Enzyme Linked Immunosorbent Assay
19	GDP	Gross Domestic Product
20	GOI	Government of India
21	HIV	Human Immuno Deficiency Virus
22	ICMR	Indian Council of Medical Research
23	IDR	Initial Drug Resistance
24	IEC	Information, Education and Communication
25	INH	Isoniazid
26	IUATLD	International Union Against Tuberculosis and Lung Diseases
27	KAP	Knowledge, Attitude and Practice
28	LT	Laboratory Technician
29	LJ	Lowenstein Jensen
30	LRS	Lala Ram Sarup Institute of TB and Respiratory Diseases
31	LWSTC	Lady Wellington State Tuberculosis Center
32	MDR	Multi Drug Resistance

33	MGIMS	Mahatma Gandhi Institute of Medical Sciences, Sevagram, Wardha
34	mm	Millimeter
35	MMR	Mass Miniature Radiography
36	MP	Modified Petroff's Method
37	<i>M.tuberculosis</i>	Mycobacterium tuberculosis
38	NGO	Non-Governmental Organization
39	NSS	National Sample Survey
40	NTI	National Tuberculosis Institute, Bangalore
41	NTP	National Tuberculosis Programme
42	PCR	Polymerase Chain Reaction
43	PHIs	Peripheral Health Institutions
44	PPD	Purified Protein Derivative
45	PPS	Population Proportion to Size
46	PTB	Pulmonary Tuberculosis
47	RNTCP	Revised National Tuberculosis Control Programme
48	SCC	Short Course Chemotherapy
49	SI	Social Investigator
50	SPSS	Statistical Package for Social Sciences
51	SSI	Statens Serum Institut
52	SR	Standard Regimen
53	STC	State Tuberculosis Center
54	STS	Senior Treatment Supervisor
55	TB	Tuberculosis
56	TBA	Traditional Birth Attendant
57	TBM	TB Meningitis
58	TO	Treatment Organizer
59	TRC	Tuberculosis Research Center, Chennai
60	TSP	Trisodium Phosphate
61	TU	Tuberculin Unit
62	USA	United States of America
63	UIP	Universal Immunization Programme
64	WHO	World Health Organization

EPIDEMIOLOGY

EPIDEMIOLOGY

001: SAMPLE SIZE REQUIREMENTS FOR TUBERCULOSIS SURVEY

VK Chadha, MS Krishnamurthy and R Channabasavaiah: NTI Bulletin 1996, 32, 3-5.

Information on the epidemiological situation of a disease is vital for instituting appropriate control strategies and also to evaluate the impact of these measures. TB disease surveys are operationally too difficult and monitoring data of DTPs in the country does not provide the requisite information on epidemiological situation of the disease. Hence epidemiological indicators like the ARTI are used to provide information on the situation of TB in a community. The ARTI is derived from the observed prevalence of infection obtained by tuberculin testing in children below 10 years of age without BCG scar. Estimation of ARTI needs a much smaller population to be investigated than that required for disease surveys and hence is feasible and affordable. The primary requisite to obtain a reliable ARTI estimate is an adequate sample size of representative children. This paper discusses the various factors involved in estimation of sample size for tuberculin surveys.

The parameters to be considered for sample size estimation are : expected prevalence of infection in the study population, desired precision, cluster size and design factor. The choice of the study subjects are BCG unvaccinated children below 10 years of age. The expected prevalence of infection can be obtained from data of earlier studies carried out in the same or adjacent areas or from characteristically similar areas. A level of precision of 10% is desirable but in case of resource constraints it may be reduced to 15%.

The formula used for estimation of sample size is: $n = Z^2_{1-\alpha/2} (1-p) / \epsilon^2 p$, where n is sample size, ϵ the relative precision, p the expected prevalence of infection, α the level of significance and z the standard error. The sample size has to be modified for cluster sampling by multiplying it with the value of the design factor (D). The design factor is estimated from the data of previous tuberculin surveys of similar design; if it is not available, D has to be approximated.

The estimated sample size for varying expected prevalence between 5-10% and relative precision between 10-15% has been provided in a tabular form in the paper

e.g: a sample size of 6915 children would be required for an expected prevalence of 10% with a relative precision of 10%. The sample size required for repeat surveys for estimating ARTI would depend on the expected change in the intervening period.

Key Words: *Sample Size; Tuberculin Survey; ARTI.*

002: EPIDEMIOLOGICAL INDICATORS OF TUBERCULOSIS

VK Chadha: NTI Bulletin 1996, 32, 31-36.

Epidemiological information on TB is essential for the formulation of appropriate control strategies. In developing countries, as health information systems do not provide reliable and accurate estimates of the disease situation, several epidemiological indicators are used for estimation of the burden of TB and assessment of its trend. Epidemiological indicators of TB, methods of their estimation and their observed rates in India are discussed in this article.

Prevalence of TB infection : This represents the proportion of individuals infected with *M. tuberculosis* at a given point of time and is expressed as percentage. It is measured through tuberculin surveys in a representative sample of individuals without BCG scars (usually children between 0-9 years). In India the prevalence of infection in the age group 0-9 years varies between 5-10% and about 40% of the entire population (all age groups combined) is infected with *M. tuberculosis*. The prevalence of infection increases with age and is higher in males.

Annual Risk (incidence) of Infection (ARTI) : ARTI is defined as the probability of acquiring new infection with *M. tuberculosis* during the course of a year. It expresses the overall impact of various factors influencing the transmission of tubercle bacilli. In the direct method, the ARTI is estimated by performing tuberculin test in a representative group of children on two occasions separated by a time interval and the proportion of tuberculin converters is estimated to calculate the annual incidence of infection. In the indirect method, the ARTI for a given period is calculated from the prevalence of infection among children of a given age. In this method ARTI can be estimated through a single tuberculin survey and is generally preferred over direct method. The ARTI in India varies between 1 to 2.5%.

Prevalence of disease : This represents the burden of TB disease and is defined as the number of existing cases at a given point of time which is expressed as proportion per unit population. Prevalence of disease is estimated through disease surveys which entails screening of a representative sample of the population using chest X-rays and subjecting those with abnormal X-rays to sputum microscopy and culture. The screening method could also include identification of chest symptoms for further investigations. It is very difficult to obtain estimates of the prevalence of extra pulmonary cases in a community. The prevalence of bacillary TB in India is estimated to be 4/1000 population.

Incidence of disease : It is defined as the number of new cases occurring over a given period of time and is expressed as a rate per unit population. Incidence of disease indicates the recent trend in the community. In developed countries, Annual TB notification rate represents the incidence of TB. In developing countries where case detection rates are low, repeat disease surveys can help in estimating the incidence of the disease. Incidence of smear positive TB is a key epidemiological indicator for evaluation of the overall TB situation and can be indirectly estimated from the estimates of the ARTI. For every 1% ARTI, the incidence of smear positive TB cases is estimated to be 50 per lakh population per year. In India, the incidence of smear positive pulmonary TB is about one third of the prevalence.

Tuberculosis mortality rate : It indicates the proportion of individuals in the community who die because of TB during the course of one year. In the pre-chemotherapy era, the TB mortality rate was used as an indicator to assess the disease trends in the community. The age distribution of new cases and TB deaths also provide an assessment of the epidemiological trends of TB

Disability Adjusted Life Years (DALYs) : This is a new epidemiological indicator that measures the burden of disease in terms of loss in healthy life years from premature death as well as disability. One DALY is equal to one lost year of healthy life. Standard schedules of expectations of life can be used for obtaining number of years of life lost as a result of death at each age. Unequal weights are given to value of life at each age : time lived in middle age is weighted as more important than extremes. The time lived with a disability is made comparable with time lost due to premature mortality by defining 7 classes of disability severity ranging from 0 (zero) for perfect

health to 1 (one) for death. However, accurate data on the cause specific mortality by complete registration of vital events, precise death certification, incidence of disease, average age of onset and duration of time lived with disability are required to report in terms of DALYs. In India, TB accounts for 3.7% of total DALYs and is the largest single cause of loss of DALYs in the productive age group of 15-59 years.

Key Words: *Epidemiology; Indicators; ARTI; Incidence; Prevalence.*

003: PREVALENCE OF UNDER-NUTRITION AMONG PERI-URBAN CHILDREN AND ITS INFLUENCE ON THE ESTIMATION OF ANNUAL RISK OF TUBERCULOSIS INFECTION

VK Chadha, HV Suryanarayana, MS Krishnamurthy, PS Jagannatha and AN Shashidhara: Indian J TB 1997, 44, 67-71.

In developing countries the ARTI is one of the key epidemiological indicators for assessment of TB situation in a community. It is derived from the prevalence of infection, obtained by subjecting a representative sample of children, preferably below 10 years of age, without BCG scar to tuberculin testing. Since the size of tuberculin reactions is likely to be affected in undernourished children, the estimates of ARTI may be influenced by the proportion of 'undernourished' children in the study group. Therefore, the data from a survey carried out among children residing in a peri-urban area to estimate the prevalence of TB disease and infection was analyzed to study the influence of under-nutrition on the estimates of ARTI.

The survey was carried out between 1990-1994 and all children aged 0-14 years residing in 60 randomly selected villages located between 19-21 kilometers from the centre of Bangalore city were registered for the study. The children were subjected to clinical examination, assessed for the presence or absence of BCG scar and their height and weight was measured. Investigations like X-ray, sputum examination, and tuberculin test were performed using standard procedures. Nutritional status of the children was assessed using Quitlet's method (Method A) and Weight for age (Method B). Of the total registered children, 12,218 were 1 to 9 years of age. Among them, 10,400 were tuberculin test read and 4,575 (44%) children without BCG scar constituted the study group. Classifying the children for nutritional status with reference

to ICMR data for healthy south Indian children by Quitlet's Index and weight for age, about 30% were found to be undernourished. Severely undernourished children constituted 2.6% of the total study population.

Based on the frequency distribution of tuberculin reactions, 5% of the overall tested children were found to be reactors at 20 mm (longitudinal diameter) demarcation level. The proportion of reactors was higher among 'normals' (5.6% by Method A and 5.5% by Method B). The value of ARTI, estimated from the proportion of reactors among 'normals' so classified by method A and method B was 1.03% and 1.01 % respectively. ARTI computed from proportion of reactors among 'over all study group' was 0.92 %.

Thus, with 30% of the children in the study group being undernourished, ARTI was under-estimated by about 9 to 11 %. The influence of under-nutrition on estimation of ARTI may vary in different communities depending upon the prevalence of under-nutrition. This aspect should be kept in mind while comparing ARTI rates between different communities of varying socio-economic status. Due consideration should also be given to any change in the nutritional status occurring in a community over a period of time while evaluating the impact of control measures.

Key Words: *Under-nutrition; ARTI; Tuberculin Test; Quitlet's Method; Weight for Age.*

004: GLOBAL TRENDS OF TUBERCULOSIS - AN EPIDEMIOLOGICAL REVIEW

VK Chadha: NTI Bulletin 1997, 33, 11-18.

Knowledge of epidemiological situation of TB in a community is vital for planning and execution of control measures, as any change in disease situation has direct relevance to the methods adopted for control. Information on the epidemiological trend of a disease in the community gives an insight into its behavioral pattern over a period of time and enables us to assess the impact of intervention programmes and also to foresee the likely future scenario. This article dwells on the epidemiological trends of TB since the pre-chemotherapy era to the resurgence in developed countries and further worsening of the problem in many developing countries.

Tuberculosis deaths in the developed countries like England, Czechoslovakia, Norway, Netherlands and USA have declined since the turn of this century. A decline in the ARTI during this period was observed in several European countries during this period. Pasteurization of

milk in the 1940s in most European countries led to a marked reduction in the transmission of bovine TB. Since chemotherapy was non-existent during this period and BCG vaccination did not affect transmission of infection, this trend in developed countries may be inferred as natural. Information on the TB situation in developing countries during the pre-chemotherapy era was scarce, though the available data suggests there was no downward trend in the TB problem.

The advent of chemotherapy in the mid-forties heralded a rapid fall in the TB mortality and the ARTI in the developed world. Improvement in living standards and TB control activities did lead to a reduction in ARTI in some developing countries. However, in most developing countries the scourge of TB continued unabated and this was largely attributable to low case finding efficiency and poor treatment programmes.

The advent of the HIV epidemic in the mid-eighties reversed the notion of TB being conquered in the developed world. The HIV epidemic also fuelled the TB problem in the developing countries where most young adults are already infected with the tubercle bacilli. As per WHO projections the maximum increase in HIV sero-prevalence was to be witnessed in the developing countries of Asia and Africa. The problem of MDR-TB which was thought to be an insignificant one outside USA was beginning to affect developing countries like Thailand.

Tuberculosis accounts for about 3 million deaths annually, the largest by any single pathogen. Most of these deaths are in the developing countries. In 1995, approximately 8.8 million new cases of active TB cases were expected to occur. India and China together contribute to 44% of the total global incidence. Most of these deaths occur in the productive age group and TB is the largest single cause of loss of DALYs. Presently, the ARTI in developed countries is estimated to be between 0.01 to 0.1% while in developing countries it varies from 1 to 2.5 %.

Assuming that the efficiency of the TB control programmes remains at current level, projections were made for the likely increase in the incidence of TB by 36% in 2000 and by 58% in 2005 compared to that of 1990.

The global TB situation is expected to worsen in the immediate future. Intensive and sustained efforts are required to decrease the reservoir of infection. WHO has declared TB a global emergency and has laid down targets of 70% case finding and 85% cure rate of those detected

in developing countries, in order to achieve a reversal in the current epidemiological trend of TB.

Key Words: *Trends; Mortality; Incidence; ARTI; HIV.*

005: RATIONALE AND A METHODOLOGY FOR ESTIMATION OF ANNUAL RISK OF INFECTION OF TUBERCULOSIS IN URBAN AREAS

VK Chadha and MS Krishnamurthy: NTI Bulletin 1997, 33, 50-55.

Baseline information on the situation of a disease in the community is vital for drafting appropriate control measures and for evaluating the effectiveness of the control strategies. Estimation of the ARTI is the accepted tool world wide for assessment of the epidemiological situation of TB. It also provides an indirect estimate of incidence of smear positive cases.

The article gleans through all the aspects of the methodology for the estimation of ARTI in urban areas right from the identification of the study population, sampling technique, choice of tuberculin, field procedures to the analysis of the data obtained from the study. The desirable study population is school entrants aged 6 years without BCG scar. However, it should be ensured that the proportion of children attending school is representative of all children of that age group in the community. Also, it is desirable to ascertain the proportion of the study population in a community with BCG scar in order to estimate the average number of children likely to be available in a school. The sample size is determined in terms of the basic sampling unit, which are school entrants aged 6 years without BCG scar and then translated into appropriate number of clusters. The term cluster denotes a school. A single stage cluster sampling technique is used and the required number of clusters for the study selected by simple random sampling from the list of all the schools in the urban areas selected for the study. The sample size (n) is calculated by the formula:

$$n = Z^2_{1-\alpha/2} (1-p) / \epsilon^2 p$$

Where ϵ is the relative precision, α the level of significance, p the expected prevalence of infection and Z the standard error of population proportion. As this sample size is applicable for simple random selection, it has to be modified for cluster sampling with the design effect (D) in order to achieve as precise an estimate as with simple random selection of children.

The tuberculin testing is to be done using ITU of PPD RT23 with tween 80, procured from BCG laboratory, Guindy and the standard procedures for testing and reading are to be observed. A pilot study may be undertaken to streamline study procedures. From histogram of the tuberculin reaction size obtained from the study, the level of demarcation between the infected and others is identified. The prevalence of infection is estimated by a weighted analysis by the formula:

$$p = \sum W_i Y_i / \sum W_i X_i$$

Where W_i the weight attached to each cluster, Y_i the number of infected in a cluster and X_i the number tested. The average ARTI is calculated by the formula:

$$ARTI = 1 - (1-p)^{1/a}$$

Where 'p' is the prevalence of infection and 'a' is the mean age of children included in the survey.

Key Words: *Prevalence; Infection; ARTI; Single Stage Cluster Sampling; Design Effect; Weighted Analysis.*

006: TUBERCULOSIS DISEASE SURVEYS IN INDIA - A PERISCOPIC VIEW

P Suganthi, AN Shashidhara and VK Chadha: NTI Bulletin 1998, 34, 49-55.

This paper reports the studies on prevalence of pulmonary TB conducted by various investigators in different parts of the country at different time periods. These are important in understanding the extent and distribution of TB in the community. Even though every survey contributed knowledge on the extent and distribution of disease that prevailed in the population, four surveys, which have influenced the course of development of anti-TB programme in India are significant.

The NSS in 1955-58 gave for the first time valid information of the magnitude of disease in the country. The prevalence of bacillary TB based on screening by microscopy and culture varied from 2-8 per 1000 population in 6 defined zones in the country. The average for the whole country was 4/1000.

In the Tumkur survey conducted by NTI during 1960-61, symptomatic screening as well as screening by x-ray was adopted and two sputum specimens were examined. The prevalence of bacillary TB was 4.1/1000. Similar prevalence was observed twelve years later. Using similar methodology, the prevalence of bacillary TB varied between 3.4 -4.06 per 1000 population in four rounds of

surveys during the longitudinal study carried out in rural Bangalore in 1961-68. It was 4.4 in 1984-86. Several rounds of surveys in a selected population of Delhi and also in North Arcot revealed a similar prevalence.

A higher prevalence of about 10.7 bacillary TB cases per 1000 was observed in 1968-71 in Chingleput district during the TB prevention trial. Similar values were later observed in Raichur and Morena districts during late eighties and early nineties.

Prevalence of sputum negative PTB (suggestive on x-ray) estimated during various studies has varied a great deal partly due to variation in the technique of interpretation of x-ray shadows.

The summarized findings of various surveys outlined in the article would give valuable information on the burden of TB in India.

Key words: TB Surveys; Prevalence

007: ESTIMATION OF ANNUAL RISK OF TUBERCULOSIS INFECTION AMONG BCG VACCINATED CHILDREN

VK Chadha, MS Krishnamurthy, AN Shashidhara, PS Jagannatha and V Magesh: **Indian J TB 1999, 46, 105-112.**

Studies on the ARTI are confined to children without BCG scar on the premise that BCG induced tuberculin sensitivity could affect the interpretation of test results. This was in accordance with the observations made in the early 1950s when the histogram of BCG induced tuberculin sensitivity in school children was found to have a unimodal distribution resembling that seen in the naturally infected population. Considering the fact that BCG vaccination coverage under the UIP is on the rise, it would be increasingly difficult to get an adequate number of children without BCG scar for tuberculin surveys. Therefore, the present study was carried out with the objective of investigating the possibility of identifying new infections with *M.tuberculosis* by including BCG vaccinated children into the study group for estimating the ARTI.

Tuberculin surveys in 16 randomly selected villages in peri-urban Bangalore using 1TU of PPD RT 23 with Tween 80 were carried out in 1990-94 (survey I) and 1996 (survey II). The study population comprised of children in the age group 0-9 years. Survey II also included all children who were aged 0-9 years at survey I and were

available for the re-survey. The maximum longitudinal diameter of the indurations was recorded 48-96 hours after the administration of the test. The data pertaining to 1342 children with BCG scar and 815 without BCG scar during survey I and 1471 children with BCG scar and 574 without BCG scar during survey II, were analyzed.

Two different techniques were deployed to examine the feasibility of estimating the ARTI by including BCG vaccinated children into the study group. In the first technique, the prevalence of infection and then the ARTI was compared between children with and without BCG scar. The estimates were made separately for the surveys I and II and found to be similar in both the groups. In other technique, the frequency distribution of differences in the tuberculin reaction size between the two surveys were plotted. In children with BCG scar, the sub group showing an increase of > 15 mm from I to II survey were found to cluster into a distinct group on the right side of the distribution. These probably represent the children newly infected with *M.tuberculosis* during the intervening period between the surveys. It was concluded that the ARTI could be estimated among BCG vaccinated children.

Key Words: ARTI; Vaccinated Children; Tuberculin Survey.

008: TUBERCULOSIS AMONG AGRICULTURAL WORKERS AND ITS CONTROL

P Jagota and VK Chadha: **ROHC-WHO Training Programme on Occupational Health in Agricultural Sector 1999, Feb, 8-12, 5-11.**

Tuberculosis is the world's foremost cause of death from a single infectious agent. The brunt of the disease is borne by those in the age group 15-59 years. An estimated one-third of the world population is infected with *M.tuberculosis*, with 95% of the cases occurring in developing countries. In India, there are 14-15 million TB patients at any point of time, which is nearly one third of the global burden of this disease. TB largely affects adults and thus has an impact on the economy of the country. In 1950 Dr. Frimodt Moller carried out the first disease survey in Madanapalle district and showed that TB was prevalent in rural areas also. The findings of the NSS (1955-58) also showed that TB was equally prevalent in rural and urban India. About 5-6% of all deaths in rural India are due to TB. In rural areas social stigma is still attached to the disease.

In a study conducted in Pune district, one out of 3 TB cases was found to be in agricultural labourers and in another study in Uttar Pradesh, one out of every 5 farm workers suffered from some kind of respiratory disease and one-fifth of the respiratory diseases were due to pulmonary TB. Most agricultural workers have poor nutritional status and live in poor housing conditions. In a study in Maharashtra, about half of the total disease prevalence in the district was contributed by agricultural workers. On extrapolating the above data nationally, it can be summarised that about 4 million agricultural workers suffer from TB at any given point of time and 1 million of them are infectious in nature and spread disease to their family members, neighbours and co-workers. All this has serious consequences on the economy and the family, and the effects of the disease on families engaged in agrarian pursuits can be devastating both financially and emotionally.

The NTP is being implemented in the country as an integral part of the general health services since 1962. The NTI evolved this programme after conducting various research studies with the objective of reducing TB deaths and detecting and treating as large number of TB patients as possible. The basic organizational unit of NTP is the DTP. The activities under the DTP are: case finding, treatment, management, recording and reporting.

It is a challenge to implement TB control activities in rural areas as the health care infrastructure is poorly developed in these areas. Financial barriers preclude people from seeking prompt treatment. Patients are not properly diagnosed and X-ray is heavily relied for diagnosis. Irregular supply of drugs, low image of public health services, lack of patient-doctor rapport and high cost of care which include travel cost, loss of wages, doctor's fees and drugs are some of the issues that merit consideration. The key staff of the DTC pay importance to clinical services and pay little attention to management and supervision of the programme in the district. Less than 50% of the patients adhere to the complete course of treatment. These are some of the constraints in controlling TB. However, these constraints can be addressed by adopting the DOTS strategy.

DOTS is the only way of ensuring high cure rates and brings about reduction in transmission of infection by rendering infectious cases non-infectious. The other measures to intensify TB control efforts are, increasing the financial support to TB control programmes, increasing awareness among public about the disease, strengthening

operations research and improving the functioning of the existing health care systems, involving NGO's and private practitioners in the programme and last but not the least, by improving the socioeconomic conditions of the rural population which includes agricultural workers.

Key Words: *Agricultural Workers; Constraints; TB Control.*

009: PREVALENCE OF PULMONARY TUBERCULOSIS AMONG CHILDREN IN A SOUTH INDIAN COMMUNITY

L Suryanarayana, HV Suryanarayana and PS Jagannatha: Indian J TB 1999, 46, 171-178.

A study on prevalence of pulmonary TB was conducted during 1991-94 among 20,063 children, aged <14 years, residing in 62 randomly selected villages situated within a 5 km belt, beyond 19 km radius from the center of Bangalore city. Of the 20,063 children, 17,477 were subjected to elucidation of history, clinical examination and tuberculin test with 1 TU PPD RT23 with Tween 80 and results read between 72-96 hours later. Of the 16,451 (94.1%), children test-read, 34.5% had tuberculin induration (longitudinal diameter) of >10 mm; 20.1% were undernourished; 3.2% had lymphnode enlargement and 4% had history of contact with a case of pulmonary TB. In all, 6,075 children with the above criteria became eligible for subsequent investigations. Of them, 1,798 (29.6%) children aged <5 years were subjected to chest X-ray, while the remaining (aged ≥5 years, 4,277(70.4%) were subjected to bacteriological (smear and culture) as well as radiological examination. From these examinations, a total of 50 radiological positive cases (11 from below 5 years and 39 from 5-14 years) and 17 bacteriological positive cases (14 culture positive + 3 smear positive) from children aged 5-14 years were detected. The diagnosis of TB in children obtained in this manner was found to be related to under-nutrition, positive reaction to tuberculin and history of contact. The prevalence of bacteriological cases was 0.15% in the age group 5-14 years and that of radiological cases 0.3% in the age group 0-14 years. These were similar to the prevalence observed in the initial round of the conventional longitudinal epidemiological survey conducted 30 years ago as well as the one conducted among the slum children of Bangalore city.

Key Words: *Prevalence; Pulmonary Tuberculosis; Children.*

010: TUBERCULIN SENSITIVITY IN BCG VACCINATED CHILDREN AND ITS IMPLICATION FOR ARTI ESTIMATION

VK Chadha, PS Jagannatha and HV Suryanarayana: Indian J TB 2000, 47, 139-146.

The traditional method of estimating the prevalence of TB infection has been through tuberculin surveys, which generally exclude BCG vaccinated children from analysis. The authors opine that the exclusion of vaccinated children could diminish the value of these surveys due to high coverage with BCG vaccination under the UIP. However, there is little available information regarding tuberculin sensitivity among vaccinated children. Hence the authors reanalyzed the data of a study undertaken by NTI, Bangalore conducted in 62 randomly selected villages around Bangalore city between 1990-94 to study the tuberculin sensitivity patterns among unvaccinated as well as BCG vaccinated children and to determine whether ARTI could be estimated among BCG vaccinated children.

A total of 13,291 children aged 0-9 years were registered through house to house census and their BCG scar status was ascertained. Tuberculin test using 1TU PPD RT23 with Tween 80 was administered and the maximum longitudinal diameter of induration was measured at about 72 hours. No tuberculin survey had ever been conducted in the study area prior to this study. The analysis was performed separately for each year of age, and for age groups 0-4 and 5-9 years. Relevant formulae were used for estimating the prevalence of infection and computing the ARTI from the prevalence.

A total of 11,132 children (5107 aged 0-4 years and 6025 aged 5-9 years) were tested. Children with BCG scar comprised 68.2% of the test read population aged 0-4 years and 47.5% of those aged 5-9 years. Overall 68.9% of the children with BCG scar had either no test reaction or reaction <10 mm in size. In the 0-4 year age group, a bimodal distribution of reaction size was observed in unvaccinated children, though it was not so in the vaccinated children. In the 5-9 year age group, the distributions were bimodal in both vaccinated and unvaccinated children. The mode on the right side of the distribution was at 25 mm in both the vaccinated and unvaccinated 5-9 year old children. Based on this mode, the prevalence of infection was estimated to be 8.08% and 8.6% among the unvaccinated and vaccinated children respectively and the respective ARTI rates were computed at 1.12% and 1.19%.

Thus, in the event of non-availability of a sufficient number of unvaccinated children for estimation of ARTI, tuberculin surveys may be conducted among 5-9 year old children by including vaccinated children into the study group. Similar studies need to be conducted among children residing in other areas with diverse geo-climatic conditions and varying rates of vaccination coverage with similar or different strains of the vaccine to authenticate the findings of this study.

Key Words: *Tuberculin Sensitivity; ARTI Estimation.*

011: SCORING METHOD FOR DIAGNOSIS OF TUBERCULOSIS IN CHILDREN-AN EVALUATION.

L Suryanarayana and PS Jagannatha: Indian J TB 2001, 48, 101-103

A scoring method for use in screening children suspected to be suffering from TB was suggested by a task group of the IUATLD. It was proposed by the authors of this article to validate the scoring to test its reliability. Accordingly, NTI conducted a study to evaluate the proposed scoring method for high TB prevalence regions, by using different diagnostic parameters on the subjects examined already in an earlier survey. The study subjects were children of 0-14 years age residing in 62 randomly selected villages around Bangalore city. Children with the following criteria, either alone or in combination with others were considered for the study - (i) tuberculin test induration of ≥ 10 mm, (ii) under-nutrition according to Quitlet's Index, (iii) symptoms suggestive of TB, (iv) lymph nodes enlargement and (v) history of contact with a case of TB. Children below 5 years of age were investigated by MMR of the chest while the older children were subjected to sputum examination in addition to the X-ray.

The Scoring system suggested by IUATLD was validated against Kenneth Stegen Jones Scoring system for childhood TB and the radiological and bacteriologically confirmed cases of the study mentioned above.

No consistency was observed in the number of cases identified by different methods. Application of the IUATLD scoring system resulted in much over-diagnosis of childhood TB. The article concludes that various scoring systems for diagnosis of TB in children need further evaluation and modification.

Key Words: *Scoring Method; Children; Diagnosis.*

012: ANNUAL RISK OF TUBERCULOSIS INFECTION IN BANGALORE CITY

VK Chadha, PS Jagannatha and SJ Savanur: *Indian J TB* 2001, 48, 63-71.

The delivery of TB control services in big cities is unsatisfactory owing to a plethora of factors like poverty, changing demography, overcrowding, improper management of cases in the private sector and the HIV epidemic. There is however, a dearth of data on the epidemiological situation of the disease in cities and hence NTI, Bangalore conducted a tuberculin survey to obtain the baseline ARTI data on TB in Bangalore city between 1996-99.

A single stage cluster sample technique was adopted for the selection of 161 schools by random sampling from a consolidated list of Government-run and Government-aided and Private schools. The study subjects were 6 and 7 year old children attending the selected schools, who were subjected to tuberculin tests following standard guidelines. The data of 9340 children (3687 without BCG scar and 5653 with BCG scar) was analyzed. The frequency distribution of reaction size (maximum transverse diameter) among children without BCG scar, with BCG scar and the overall study group were plotted separately. The antimode was not clear in any of the three distributions though a bimodal distribution was evident in that pertaining to the children without BCG scar. The mode of reactors attributable to tuberculous infection was observed at 22 mm, in children without BCG scar and was similar to that obtained on tuberculin testing of 192 smear positive pulmonary TB cases. Therefore, the prevalence of infection was estimated by mirror image technique using the mode at 22 mm, in children without BCG scar and the overall study group. The weighted prevalence of infection was 11.03% in children without BCG scar, 11.11% in children with BCG scar and 11.10% in the overall study group. The estimated prevalence of infection in children with and without BCG scar was statistically similar. The ARTI computed from the prevalence estimates were 1.66% in children without BCG scar and 1.67% both in children with BCG scar and the overall study group. The study also indicated that children studying in Government run and Government aided schools were more likely to be infected than those attending Private schools.

The ARTI in Bangalore city was higher than that in the surrounding peri-urban and rural areas suggesting the need for improving the TB control measures. Another fall

out of the study was the feasibility of including BCG vaccinated children in ARTI studies.

Key Words: ARTI; Prevalence; Infection.

013: ANNUAL RISK OF TUBERCULOUS INFECTION IN RURAL AREAS OF JUNAGADH DISTRICT

VK Chadha, PS Vaidyanathan and PS Jagannatha: *J Com Dis* 2001, 33, 231-240.

Accounting for a death every minute, TB continues to ravage India. India shoulders about one third of the global burden of this disease. The knowledge of the magnitude of the burden of TB in the community will help public health planners in drafting appropriate control measures. As TB disease surveys are prohibitively expensive and TB infection is far more prevalent than the disease, prevalence of infection and ARTI are the preferred epidemiological indicators for assessing the situation of TB in the community. These parameters are computed from the data obtained from tuberculin surveys in a representative sample of young children because infection with environmental mycobacteria is less common in them and the infection in children is a good indicator of recent levels of transmission of infection. The ARTI indicates the average probability of an uninfected person getting infected or re-infected with *M.tuberculosis* during the course of one year. It is the earliest epidemiological parameter to be affected following any alteration in the TB situation in the community induced by changes in the load of infectious cases and the efficacy of TB control measures.

Insufficient epidemiological data on TB in India prompted the NTI to embark upon a Nation wide survey to estimate the ARTI in different parts of the country. The survey in Junagadh district, one of the 26 districts drafted under the nation wide survey is reported in this paper. Junagadh is a dry and arid district situated in the Saurashtra region of Gujarat. The field work in the rural areas of Junagadh district was conducted in 80 clusters selected by the PPS method. A cluster in a rural area constituted a village. The field work was carried out from 1st February 2000 to 6th June 2000. In each cluster 85 children of 1-9 years of age were registered and subjected for tuberculin testing and reading by standardized tuberculin testers and readers.

The analysis of 3,164 children not displaying scar of the BCG vaccination showed that the prevalence of infection was 4.16% (CI: 3.17-5.14) and from this data the ARTI was computed as 0.73% (CI: 0.55-0.91). The inclusion of vaccinated children into the study group yielded similar results. The ARTI in Junagadh district is lesser than that in several other parts of India which is probably in consonance with its better socio-economic development.

Key Words: *Epidemiological Indicator; ARTI; Prevalence; Infection; Tuberculin Survey.*

014: MIXTURE MODEL FOR ANALYSIS OF TUBERCULIN SURVEYS

SJ Savanur, VK Chadha and PS Jagannatha: Indian J TB 2002, 49, 147-152

Annual Risk of TB infection is one of the key epidemiological indicators for assessment of TB situation in a given community and also to assess the impact of disease control programs. The ARTI is estimated through statistically planned tuberculin surveys among children without BCG scar. In a given community, individuals respond with different levels of tuberculin sensitivity and can be broadly classified into 3 sub-groups, individuals either responding (i) with no reaction or small size reactions to tuberculin test, (ii) moderate size reactions and (iii) larger reactions. Small and moderate size reactions could be caused by *M.tuberculosis* or to environmental mycobacteria or BCG induced sensitivity. Large reactions are usually attributable to infection caused by *M.tuberculosis*.

The estimation of prevalence of TB infection requires determination of the proportion of the sub-group infected with *M.tuberculosis*. The conventional method of analyzing the tuberculin survey data consists of presentation of tuberculin reaction sizes as a frequency distribution curve and locating the anti-mode on the curve which is considered as the cut-off point for identification of the subgroup infected with *M.tuberculosis*. However, a clear anti-mode is not always discernible, especially in communities with high prevalence of cross-sensitivity to tuberculin. Identification of the mode poses further problems in communities with low prevalence of tuberculous infection. Therefore, epidemiologists have to adopt other statistical techniques for estimating the proportion of individuals infected with *M.tuberculosis* with the highest possible

accuracy. The technique of mixture model analysis is one such possible statistical approach. The mixture analysis has been used in other scientific fields for estimating the proportions for various subgroups in a given distribution but has rarely been used for analysis of health studies. The present investigation was undertaken with the following objectives: -

1. To estimate the prevalence of TB infection by mixture model analysis of the data obtained in 4 tuberculin surveys, of which 3 surveys were undertaken by NTI, Bangalore.
2. To compare the estimates of prevalence of infection obtained by mixture model analysis and conventional methods.

The tuberculin reaction sizes in a given distribution were assumed to represent a mixture of three subgroups, each following a normal distribution. The maximum likelihood estimates of the parameters of the component distribution and the proportion of the sub-groups in the study population were obtained using EM-algorithm. The estimates of prevalence of TB infection obtained by mixture model analysis were compared with the estimates based on locating the cut-off point (anti-mode) or the mode of reactions attributable to infection with *M.tuberculosis*.

In the 7 data sets from four tuberculin surveys considered for the present analysis, normal distributions were assumed for all three sub-groups. The mathematical fit to tuberculin reactions of the subgroups having no tuberculin sensitivity followed right limb of normal distribution with the percentage of reactors falling smoothly with the rise in the size of reaction. Various studies have demonstrated that tuberculin reactions in the infected group follow normal distribution. The cross reactions may be attributable, as explained above, to a variety of non-environmental mycobacterial infections and to BCG induced tuberculin sensitivity among vaccinated children not showing BCG scar. All these cross-reactions were dealt with as a single normal distribution. In the present analysis the estimated ARTI rates by mixture method and those based on mode or antimode were found to be concordant. These were exactly the same for the 4 data sets and there were only slight differences for the other 3 data sets.

The mixture model analysis can be a very useful tool for the analysis of data obtained from tuberculin

surveys, especially when there is difficulty in identification of the anti-mode or the mode of reactions attributable to infection with *M.tuberculosis*.

Key Words: *Mixture Model Analysis; Maximum Likelihood Estimate; EM-algorithm; Prevalence; Infection.*

015: ANNUAL RISK OF TUBERCULOUS INFECTION IN RURAL AREAS OF UTTAR PRADESH, INDIA

VK Chadha, PS Jagannatha, PS Vaidyanathan, S Singh and Lakshminarayana: *Int J Tuberc Lung Dis* 2003, 7, 528-535.

The article pertains to the survey conducted in rural areas of the districts of Rae Bareli, Hardoi and Jaunpur located in the state of Uttar Pradesh which was a part of the study area in the northern zone of the nation wide tuberculin survey. The sample size of test read children was sufficient to make estimates of the prevalence of infection specific to the rural areas of the aforesaid 3 districts. The objectives of the study was to estimate the prevalence of infection among children without BCG scar in the age group 1-9 years, compute ARTI from the estimated prevalence and to compare the tuberculin reactions among children with and without BCG scar.

The study was conducted in 86 villages of Rae Bareli, 100 villages in Hardoi and 124 villages in Jaunpur district between April 2000 to July 2001. The study population were children aged 1-9 years who were tuberculin tested with 1TU PPD RT23 with Tween 80 procured from BCG laboratory, Guindy and the maximum transverse diameter of the induration were read after 72 hrs. The survey was conducted by a trained team of health workers who were supervised by experienced team leaders from NTI, Bangalore.

The proportion of children with BCG scar was 31% in Rae Bareli, 26% in Hardoi and 30% in Jaunpur district. The prevalence of infection was estimated in children without BCG scar based on the cut-off point identified on the histogram of reaction size. The exercise was done separately for the 3 districts. The cut-off point separating the infected children from the others was discernable at 13/14 mm in Rae Bareli and Jaunpur districts while it was at 12/13 mm in Hardoi district. Prevalence of infection was estimated for these different cut off points - 12, 13 and 14 mm. Using the cut-off point of 14 mm the prevalence of infection in Rae Bareli district was 13.03% (95% C.I-12.99-13.07), while in Hardoi it was 10.19% (95%

C.I- 10.18-10.20) and in Jaunpur it was 8.38% (95% C.I-8.37-8.40). The ARTI was computed from the estimated prevalence and was 2.3% in Rae Bareli, 1.9% in Hardoi and 1.5% in Jaunpur district. The results of the survey from the 3 districts were pooled to study the trends in ARTI with age. The risk of infection was observed to follow an increasing trend with age. The analysis of the data in children with BCG scar suggests the feasibility of including them in tuberculin surveys to estimate ARTI.

The study was the first of its kind to be conducted in any part of Uttar Pradesh and the estimates of ARTI indicate a high rate of transmission of tuberculous infection. This could be a fallout of the poor performance of the NTP, unsatisfactory delivery of primary health care services in general and low coverage of the population by the DOTS strategy at present. In the study, the risk of infection was found to increase with age probably owing to the higher risk of exposure with time but this aspect needs further investigation. The prospect of the inclusion of BCG vaccinated children in tuberculin surveys for estimating ARTI should also be studied further though the results of this study suggest that they may be included. The article concludes by emphasizing the necessity of drastic attitudinal change in stakeholders towards the delivery of anti-TB services and intensification of efforts to quell the disease.

Key Words: *Infection; Annual Risk; BCG.*

016: ANNUAL RISK OF TUBERCULOUS INFECTION IN WESTERN ZONE OF INDIA

VK Chadha, PS Vaidyanathan, PS Jagannatha, KP Unnikrishnan, SJ Savanur and PA Mini: *Int J Tuberc Lung Dis* 2003, 7, 536-542.

Epidemiological information on the situation of TB in many parts of India was by and large unknown prior to the nation wide survey on the ARTI conducted by NTI, Bangalore. For the purpose of the survey, the country was stratified into four zones (north, south, east and west), each having about a fourth of the country's population. The survey was designed to obtain estimates of the average ARTI in each of the four zones. The article pertains to the study conducted in the western zone.

The study in the western zone which comprised of the states of Gujarat, Maharashtra, Rajasthan and Madhya Pradesh was conducted between February 2000 and January 2002. The sample size was estimated as 12,000 tuberculin test read children without BCG scar residing in 600 clusters – a cluster in a rural area being a village while that in the urban, the census enumeration block. Using appropriate

statistical methods, the study was conducted in 418 rural and 182 urban clusters located in the districts of Junagadh (Gujarat), Nagpur, Thane and Ratnagiri (Maharashtra), Kota (Rajasthan) and Jabhua (Madhya Pradesh). The study subjects were children between 1-9 years of age who were subjected to tuberculin testing with 1 TU PPD RT23 with Tween 80 procured from BCG laboratory, Guindy. The transverse diameter of induration was measured after 72 hours. The field work was constantly supervised by experienced team leaders from NTI.

The analysis was confined to children without BCG scar and the histograms of the tuberculin reaction size were plotted separately for the rural and urban strata. Reactions equal to or greater than the identified cut off point were considered attributable to infection with tubercle bacilli. The proportion of infected children in the rural and urban areas of each district was estimated as weighted average of cluster proportions, with the weight being the inverse of the initial probability of selection of the cluster. The proportion of infected children in the rural and urban strata of the entire zone was further estimated by combining the respective district estimates, using the proportion of district population (rural, urban) in the zone as the weight. The zonal estimate of the prevalence of infection was obtained by pooling the rural and urban estimates and the ARTI was computed from the estimated prevalence. The data was analyzed using SPSS software.

In all, 48,473 children were test read and the proportion of those with BCG scar was 52%. The data pertaining to 22,259 children without BCG scar was analyzed after excluding those with BCG scar, doubtful scar status and those tested unsatisfactorily. The frequency distribution of tuberculin reaction size in children without BCG scar was bimodal in both the rural and urban strata with the mode of reactions attributable to infection with tubercle bacilli at 20 mm and there was a suggestion of antimode at 15 mm. Therefore, all reactions ≥ 15 mm in size were considered attributable to infection with tubercle bacilli. The tuberculin reaction sizes among 594 smear positive pulmonary TB patients revealed an identical mode at 20 mm. The prevalence of infection in western zone was estimated at 9.3% (95% C.I.: 6.8-11.8) and the ARTI computed from the estimated prevalence was 1.8% (95% C.I.: 1.3-2.3). The ARTI in urban areas was more than that in rural areas. There was no significance difference in proportion of infected between boys and girls.

The results of the survey would serve as the baseline data for evaluating the impact of disease control measures.

The estimated ARTI of 1.8% indicates a high rate of transmission of infection in the community which is higher than that in many developing countries. The high ARTI was in consonance with a poorly functioning NTP in the past. To alter the scenario, the case detection rates need to be improved, DOTS strategy made universally accessible and partnerships forged with NGOs and private practitioners.

Key Words: *Infection; Tuberculin Survey; Annual Risk; India.*

017: EPIDEMIOLOGICAL SITUATION OF TUBERCULOSIS IN INDIA

VK Chadha: J Indian Med Assoc 2003, 101, 144-145

Epidemiological information of TB is essential for drafting appropriate disease control strategies and is also important for assessing the impact of intervention programmes.

The NSS conducted by the ICMR on the prevalence of PTB in 1955-58 provided valuable insights into the disease situation in the community. The prevalence of sputum positive PTB was estimated at 4 per 1000 population which was similar in rural and urban areas and was more in males especially in those above the age of 35. The inputs from the study were of great help in formulation of the NTP in 1962. Similar results were obtained subsequently from studies in Tumkur district (1960s and 70s), longitudinal study in Bangalore (1960s-80s) and field practice area of New Delhi TB Center (1962-92). A much higher prevalence rate of 10.68 per 1000 population was obtained in the Chingleput BCG prevention trial area. There have been other studies on disease prevalence, conducted in North Arcot, Wardha, Raichur and Morena districts.

The incidence of sputum positive PTB was found to be about one third of the prevalence in longitudinal studies of NTI, Bangalore and Tuberculosis Research Center (TRC), Chennai.

The ARTI is the key parameter for the epidemiological study of TB in developing countries. The author has comprehensively depicted the ARTI culled from various ARTI studies conducted at different points of time but predominantly restricted to pockets in southern India with the notable exception of the nation wide ARTI study undertaken by NTI. The ARTI obtained from these studies varied between 1.4-2%. The TB programme has assumed the ARTI of 1.7% to fix targets for case detection.

The mortality due to TB is not a good epidemiological indicator in the post-chemotherapy era. It is estimated that a person dies due to TB every minute though the only study on TB mortality rate at the community level which was revealed it to be 85 per lakh population during the longitudinal study conducted by NTI

There are about 2 million new cases of TB occurring in the country every year (0.9 million each of smear positive and smear negative cases of PTB and 0.2 million cases of extra-pulmonary TB). The advent of the HIV epidemic, drug resistance and rapid urbanization are expected to worsen the TB situation. However, with the strides made by the RNTCP, there are good prospects of decreasing the burden of TB in India.

Key Words: *Epidemiological Information; ARTI.*

018: ANNUAL RISK OF TUBERCULOUS INFECTION IN THE NORTHERN ZONE OF INDIA

VK Chadha, PS Vaidyanathan, PS Jagannatha, KP Unnikrishnan and PA Mini: Bull WHO 2003, 81, 573-580

The NTI, Bangalore decided to conduct a nation wide tuberculin survey to estimate the ARTI, as information on the prevailing epidemiological status of TB was largely unknown for most parts of the country. The paper pertains to the study in northern zone, which was one of the 4 zones into which the country was stratified for the purpose of the survey.

The northern zone comprised of the states of Himachal Pradesh, Jammu and Kashmir, Punjab, Haryana, Uttar Pradesh and Delhi. The computation of the sample size and the sampling of the population to be studied were determined using appropriate statistical techniques. The study area consisted of 600 rural and urban clusters (denoted by a village in a rural area and a census enumeration block in an urban area) located in the districts of Rae Bareilly, Hardoi, Jaunpur, Gurdaspur, Kangra and Delhi.

The fieldwork was conducted between April 2000 to August 2001. The study subjects were children between 1-9 years of age. In each cluster, 85 children were subjected to tuberculin testing using 1TU PPD RT23 with Tween 80 procured from BCG laboratory, Guindy and the maximum transverse diameter of induration was measured 72 hours later. The field work was performed by a team of trained

health workers who were constantly supervised by experienced team leaders from NTI.

In all, 45% of the test read children had a BCG scar and it was more prevalent in urban children compared to those from rural areas. The data pertaining to 25,816 children without BCG scar was analyzed and the frequency distribution of the reactions among them plotted. Reactions equal to or greater than the identified cut-off point were considered attributable to infection with tubercle bacilli. The frequency distribution of the reaction size was bimodal with the mode of reactions attributable to infection with tubercle bacilli at 20 mm and an anti-mode was apparent at 14 mm. Similar distributions were obtained when tuberculin reaction sizes were plotted individually for rural and urban strata. The mode at 20 mm was corroborated by the identical mode obtained from the frequency distribution of tuberculin reaction size among 493 test read cases of smear positive pulmonary TB. Using the anti-mode at 14 mm as the cut-off point, the prevalence of infection in the zone was estimated as 10.3% (95% C.I. 8.4-12.2) and the ARTI computed from the estimated prevalence was 1.9% (95% C.I. 1.5-2.2). Similar estimates were made using the mirror image technique considering the mode at 20 mm. The prevalence of infection and thence the ARTI was more in urban children compared to those in the rural stratum. Also a lower risk of infection was observed in children between 1-4 years compared to those between 5-9 years of age.

The results provide the baseline data on the epidemiological situation of TB in northern zone. The ARTI was higher than the estimates obtained from other developing countries in recent times. It was not possible to comment on the contribution of the HIV epidemic. The estimated ARTI of 1.9% indicates the presence of a large number of infectious cases in the community. This may be due to the unsatisfactory performance of the NTP which was in vogue in large tracts of the zone. As the DOTS strategy was available to only a quarter of the population of northern zone it is important to make it fully accessible to all, considering the fact that the areas covered by RNTCP performed better in terms of case detection and cure. The intensification of the TB control measures on a sustained long-term basis is necessary as no immediate respite from the scourge is possible as the incidence of new cases will continue to remain high in the near future due to the high ARTI.

Key Words: *Infection; Tuberculin Survey; Annual Risk; North Zone.*

019: ANNUAL RISK OF TUBERCULOUS INFECTION IN THREE DISTRICTS OF MAHARASHTRA

VK Chadha, PS Vaidyanathan, Pratibha Narang, SJ Savanur, DK Menderitta and Lakshminarayana: *Indian J TB* 2003, 50, 125-132.

The article pertains to the survey conducted in the rural and urban areas of three districts of Maharashtra: Nagpur, Thane and Ratnagiri, which were a part of the study area in the western zone of the nationwide tuberculin survey undertaken by NTI, Bangalore. The sample size of the test read children was sufficient to make estimates of the prevalence of infection specific to these districts. The ARTI was computed from the estimated prevalence of infection among children aged 1-9 years.

The study area comprised of rural and urban clusters (a rural cluster was denoted by a village and an urban cluster was a census enumeration block) of the three districts which were selected by PPS sampling. The study was conducted in 62 rural and 52 urban clusters of Nagpur, 92 rural and 86 urban clusters of Thane and 69 rural and 3 urban clusters of Ratnagiri district between August 2000 – January, 2002 with the support of MGIMS, Wardha. The study population was children aged 1-9 years. They were tuberculin tested with 1TU PPD RT23 with tween 80 procured from BCG Laboratory, Guindy and the maximum transverse diameter of the reactions were read after 72 hours.

The frequency distribution of tuberculin reaction size obtained from the rural and urban strata of each district was illustrated separately and the anti-mode for identification of infection with tubercle bacilli was located. Reactions greater than or equal to the identified anti-mode were considered attributable to infection with tubercle bacilli. In each strata, the prevalence of infection was estimated in children without BCG scar and irrespective of BCG scar based on the cut - off point identified on the histogram of reaction size. All the distributions were bimodal with the anti-mode at 15 mm. All reactions ≥ 15 mm were therefore considered attributable to infection with tubercle bacilli. The prevalence of infection in rural and urban areas of Nagpur was 6.36 (CI: 6.34-6.38) and 8.47 (CI: 8.44-8.50) respectively, in rural and urban areas of Thane district it was 8.08 (CI: 8.07-8.10) and 15.78 (CI: 15.75-15.80) respectively and 9.74 (CI: 9.71-9.77) in rural areas of Ratnagiri. The ARTI computed from the estimated prevalence was 1.2% and 1.6% respectively in rural and

urban areas of Nagpur, 1.6% and 3.3% respectively in rural and urban areas of Thane and 1.8% in rural areas of Ratnagiri. The data for urban areas of Ratnagiri was not analyzed due to insufficient sample of test read children.

The ARTI estimates for the 3 districts were atleast 10 to 33 times higher than those reported from developed nations. The estimated ARTI rates were found to vary between the areas studied and were significantly higher in urban compared to rural areas which could be attributable to urban congestion, phenomenal population growth in Thane city, mushrooming of slums, poor anti-TB services and the possible contribution of HIV infection. However, effective and sustained TB control measures adopting the DOTS strategy can bring the disease situation under control.

Key Words: *Tuberculin Test; Reaction Size; Prevalence; Tuberculous Infection; Annual Risk.*

020: PPD RT23 FOR TUBERCULIN SURVEYS IN INDIA

VK Chadha, PS Jagannatha, PS Vaidyanathan and P Jagota: *Int J Tuberc Lung Dis* 2003, 7, 172-179.

Most tuberculin surveys conducted in India have used 1TU of PPD RT23 with Tween 80 indented from BCG Laboratory, Guindy, Chennai. The study was conducted with objective of validating the use of 1TU PPD RT23 with Tween 80 prepared by BCG Laboratory Guindy from the freeze-dried seed lot procured from Statens Serum Institute (SSI), Copenhagen.

The study was conducted between April 1998 to August 2000 in two TB sanatoria located in Bangalore City and rural areas of Bangalore district. The study subjects were smear positive PTB cases. The study subjects were subjected to dual tuberculin testing as follows: (i) 75 cases were tested using 2TU PPD RT23 with Tween 80 dilutions prepared at Guindy (Dilution-G) and 2TU PPD RT23 with Tween 80 dilutions prepared at SSI (Dilution-S)-(Group I). (ii) 138 cases were tuberculin tested with 1TU and 2TU of Dilution-G- (Group-II). In addition to the above 2 groups, 1430 apparently healthy children between 5-9 years of age residing in rural areas of Bangalore district were dually administered 1TU and 2TU of tuberculin Dilution-G (Group III). The test sites were the volar aspect of the forearms which were allocated randomly for the testing, using the double blind technique. HIV positive cases and children with history of acute fever or skin rash in the recent past were excluded from the

study. The sensitivity of different dilutions were compared using appropriate statistical methods. Also, the tuberculin results of different surveys conducted in India using 1TU PPD RT23 with Tween 80 were compared to ascertain if there was any shift in the mode of reactions attributable to infection with *M.tuberculosis*. The modes and means of tuberculin reaction sizes in TB patients obtained from different studies in India using 1TU and 2TU Dilution-G and similar doses of Dilution-S in other countries were also examined.

The data from 63 cases in Group I, 124 in Group II and 1338 children from Group III was analyzed after excluding those with unsatisfactory test and absentees for reading. The differences in the sensitivity using the different preparations were found to be small and statistically insignificant. A higher proportion of reactions in the 10-14 mm and 15+ mm categories was observed in children to 2TU when compared to 1TU of Dilution-G. This could lower the specificity of 2TU in our country where non-specific sensitivity is common. Finally, studies in India and other countries do not suggest any loss in potency of 1TU PPD RT23 with Tween 80.

The results of the study thus puts paid to rest various contentious issues stemming from reports which mention that the dilutions of PPD RT23 prepared locally in some countries was inferior to that prepared at SSI, the rational of the use of the dose of 1TU and not 2TU of the PPD and aspersions on the potency of 1TU PPD RT23 over the years. The authors conclude that 1TU dilutions of PPD RT23 with Tween80 procured from BCG laboratory Guindy may be continued to be used for tuberculin surveys in India.

Key Words: *PPD RT23 with Tween80; Sensitivity; Specificity; Tuberculin Reaction Sizes.*

021: ANNUAL RISK OF TUBERCULOUS INFECTION IN KHAMMAM - A TRIBAL DISTRICT OF ANDHRA PRADESH

VK Chadha, A Banerjee, M Ibrahim, PS Jagannatha and P Kumar: Indian J Communicable diseases 2003, 35, 198-205.

A tuberculin survey to estimate annual risk of tuberculous infection was conducted in Khammam tribal district during 2001-2002. A total of 8637 children were test-read - 2991 without BCG scar and 5442 with BCG scar. The tests were performed using 1TU PPD RT23 and

the maximum transverse diameter of induration was recorded at about 72 hours after the test. Based on the frequency distribution of reaction size, cut-off point for infection with tubercle bacilli was considered at 12 mm. Using this criteria, the prevalence of infection was estimated at 11.8% among children without BCG scar and 10.6% among children with BCG scar. This difference was found to be statistically insignificant. ARTI rates computed from the prevalence estimates among children without and with BCG scar were 1.6% and 1.5% respectively. It was computed as 1.5% from the prevalence in the combined group i.e. irrespective of BCG scar status.

Key words: *Infection; Prevalence; Annual Risk; Tuberculin Test.*

022: PREVALENCE OF TUBERCULOUS INFECTION IN INDIA – a review of the published data

P Suganthi: NTI Bulletin 2003, 39, 15-23

Some of the important findings of various tuberculin surveys carried out in India from 1951 till 1999 are presented in this article. Such surveys carried out in representative sample of the population provide estimates of prevalence and ARTI that are useful in planning programs for control of TB in the community.

About 40% of the population in all ages of both sexes were found to be infected in Tumkur district of Karnataka, during 1960-61. This proportion was 50% in Chingleput during 1968-71. During 1970's, in a study conducted among the study population of 6-25 years in Kashmir valley, the proportion of those infected was around 41.41%. In the Longitudinal study conducted by NTI from 1961-68, the overall prevalence of infection ranged from 29.3 to 30.4% from the first to the fourth survey among all age groups. The findings of another survey conducted during 1977-78 in Bangalore rural district revealed that the prevalence of infection among all age groups was 65.2%.

Also a very high proportion of infection of 16.9% was found in children aged between 0-9 years in Morena district of Madhya Pradesh. A study in randomly selected sample of schools in Bangalore city was conducted by NTI during 1996-99 among children aged 6-7 years. The study revealed that the overall prevalence of infection was 11.10% - 11.03% among children without BCG scar and 11.11% among children with BCG scar. The prevalence of

infection among children with BCG scar was similar to that of children without BCG scar. The prevalence of infection in younger age groups is an indicator of the recent transmission of infection due to tubercle bacilli.

The result of the above surveys are strictly not comparable in view of the variations in techniques, type of tuberculin used, tuberculin testing and reading, dosages and the level of demarcation decided for labeling the presence of tuberculous infection. However these surveys conducted over different periods of time in different parts of the country give important information on the epidemiological situation of TB in our country.

Keywords: *Tuberculin Test; Prevalence; Infection*

023: THE ANNUAL RISK OF TUBERCULOUS INFECTION IN THE EASTERN ZONE OF INDIA

VK Chadha, P Kumar, J Gupta, PS Jagannatha, Lakshminarayana, V Magesh, A Jameel, S Singh, RK Srivastava, D Narayanaprasad and PS Vaidyanathan: Int J Tuberc Lung Dis 2004, 8, 537-544.

The article reports on the community based cross-sectional tuberculin survey executed in the eastern zone of India, which was a subset of the study area of the nationwide study on the ARTI. The importance of this study is highlighted by the fact that it was the first tuberculin survey to be scientifically conducted in the eastern parts of India. The eastern zone comprised of states of Jharkhand, Bihar, Orissa, West Bengal, Sikkim, Arunachal Pradesh, Assam, Meghalaya, Tripura, Nagaland, Manipur and Mizoram. The study was conducted in 387 rural clusters and 128 urban clusters located in the districts of Samastipur (Bihar), Purbi Singhbhum (Jharkhand), Papum Pare (Arunachal Pradesh), Cuttack (Orissa), Kamrup (Assam), East District (Sikkim), Jalpaiguri and Bardhaman (West Bengal). The selection of the districts and clusters was based on a stratified two-stage sampling procedure.

During the study period between June 2001 to January 2003, 40,964 children were subjected to the standard tuberculin test using 1TU PPD RT23 with Tween 80 and the maximum transverse diameter of induration was measured about 72 hours later. The BCG scar was observed in 51.5% of the test-read children. The frequency distribution of tuberculin reaction size among 19,332 children without BCG scar was found to be bimodal, with mode of reactions attributable to infection with tubercle

bacilli at 20 mm. There was a suggestion of an anti-mode at 16 mm in the urban stratum and 16/17 mm in the rural stratum. These findings were also corroborated by the modal value at 20 mm obtained from the tuberculin reaction size among 362 smear positive pulmonary TB cases. The prevalence of infection estimated by both the cut-off point and mirror image methods was 6.9%. The average ARTI for the zone was 1.3% and the magnitude of the risk was significantly higher in urban compared to rural children. The high rate of ARTI suggests a need for committed and sustained tuberculosis control services. The result of the ARTI in this area provide a baseline to evaluate the trends of the disease in the future.

Keywords: *Infection; Tuberculin Survey; Annual Risk; India.*

024: THE ANNUAL RISK OF TUBERCULOUS INFECTION IN ORISSA STATE, INDIA

AN Shashidhara, VK Chadha, PS Jagannatha, TK Ray and RN Mania: Int J Tuberc Lung Dis 2004, 8, 545-551.

As there was no baseline data on the size and extent of the epidemiological situation of TB in the state of Orissa, it was deemed important to conduct a study to obtain reliable information indicating the situation of TB in that state. Accordingly, a tuberculin survey was conducted to estimate the prevalence of tuberculous infection among children of 1-9 years of age and compute the ARTI. The cross-sectional community based survey was carried out between May 2002 and February 2003 by DANTB, Orissa under the guidance of the NTI, Bangalore.

A stratified cluster sampling technique was adopted for selecting 8 districts out of the 30 districts in the state. The districts were stratified into tribal, coastal and others. In each stratum, one fourth of districts were selected by PPS method. Thus 3 districts (Mayurbhanj, Sundargarh, Gajapati) were selected from the tribal strata, three (Ganjam, Balasore, Bhadrak) from the coastal strata and 2 (Angul, Bargarh) from the other stratum. A total of 490 clusters (422 rural and 68 urban) were distributed into these 3 strata in proportion to their population. Within the districts, selection of clusters was done by simple random sampling.

In all 25,281 children were registered into the study of which 14,655 (58%) had BCG scar and 10,626 (42%)

only were without BCG scar. Child cards were prepared for the unvaccinated children and they were subjected to the standard tuberculin test with 1TU of PPD RT23 with Tween 80. Reading of the reactions was done about 72 hrs later by measuring the maximum transverse diameter of the induration.

The data pertaining to 10,191 satisfactorily test-read children was analyzed. Based on the frequency distribution of the tuberculin reaction sizes, the prevalence of infection was estimated both by the cut-off-point method and the mirror image technique. By cut-of-point method, the prevalence of infection in the state of Orissa as a whole was estimated at 9.7% and ARTI was computed at 1.7%. Using the mirror image technique, the prevalence of infection was estimated at 10.2% and ARTI computed at 1.8%. The magnitude of risk was higher in children residing in urban areas compared to those in rural areas and it was more in females than males.

The average ARTI estimated in the present study was higher than that estimated for the eastern zone during the nationwide tuberculin survey but it was within the range of 95% confidence estimates for eastern zone. The ARTI in Orissa indicates a high rate of transmission of infection and the expected incidence of smear positive TB cases would be about 85-90 per 100,000 population. The high rate of transmission of infection was a fall out of the unsatisfactory performance of the TB control efforts in the past. However, sustained and concerted TB control efforts over a reasonable period of time can reduce the level of transmission of the infection.

Key words: *Infection; Prevalence; Tuberculin Skin Test; Annual Risk; India.*

025: CAN BCG VACCINATED CHILDREN BE INCLUDED FOR TUBERCULIN SURVEYS TO ESTIMATE ANNUAL RISK OF TUBERCULOUS INFECTION IN INDIA?

VK Chadha, PS Jagannatha and P Kumar: Int J Tuberc Lung Dis 2004, 8, 1437-1442.

Tuberculin surveys have not only become operationally difficult in terms of obtaining adequate sample size of unvaccinated children but concerns have also been made on the applicability of the results obtained from the unvaccinated children to the overall population in that age group. In an earlier study in Bangalore district, the majority of children vaccinated under the Expanded Programme on

Immunization (EPI) elicited low levels of tuberculin sensitivity and the prevalence of the infection estimated among unvaccinated and vaccinated children was similar. However, since these observations pertained to a small area, the data from the nation-wide tuberculin survey was analyzed to examine whether the estimates of the prevalence of tuberculous infection in children with BCG scar was similar to that obtained in children without BCG scar.

The study subjects were 1-9 year old children who were tuberculin test-read using 1 TU PPD RT23 with Tween 80 irrespective of their BCG scar status. The readers were blinded to the BCG scar status at time of the reading of the maximum transverse diameter of the induration of the reactions, which was performed about 72 hours after administering the tuberculin test. The children resided in the rural areas of the northern, western and eastern zones of India. The frequency distributions of tuberculin reaction size were compared for children with and without BCG scar separately for 1-4 year and 5-9 year age groups. The histograms were separately prepared for each of the 3 zones. It was not possible to estimate the prevalence of infection by the cut off point method from the frequency distribution of tuberculin reaction pertaining to children with BCG scar due to lack of anti-modes. In the majority of the distributions, the modes on the right side of the distribution, whenever discernible, were uniformly located at 20 mm, especially in the 5-9 years age group, immaterial of the BCG scar status. However, such modes were not clearly visible in the 1-4 age group in all 3 zones. The modal value of 20 mm was also corroborated from the similar results obtained from earlier studies among smear positive TB cases. Hence, it was reasonable to presume that the reactions due to tuberculous infection may be distributed around the modal value at 20 mm.

In children aged 1-4 years, the estimated prevalence of infection was respectively 3.5%, 3.8% and 3.6% among children without BCG scar, and 4.8%, 4.7% and 4.5% among children with BCG scar in the western, northern, and eastern zones. In those aged 5-9 years, the estimated prevalence was respectively 10.4%, 11.0% and 9.1% among children without BCG scar and 11%, 11.9% and 8.7% among children with BCG scar in the three zones. Thus, in children aged 1-4 years, the estimated prevalence among those with BCG scar was considerably higher than in those without BCG scar. This difference was small in those aged 5-9 years.

Tuberculin surveys may be conducted irrespective of BCG scar status among children aged 5-9 years and the

prevalence of infection may be estimated using the mirror-image technique. However, the applicability of the findings should be re-evaluated in case of any change in the BCG vaccination policy and also in settings where BCG vaccine is prepared using strains other than Danish 1331.

Keywords: *Infection; Prevalence; ARTI; Tuberculin Survey; BCG Vaccination.*

026: ANNUAL RISK OF TUBERCULOUS INFECTION IN RURAL AREAS OF KOTA DISTRICT

PS Vaidyanathan, VK Chadha, P Kumar, PS Jagannatha and G Umadevi: Indian J TB 2004, 51, 123-130.

A nation-wide tuberculin study was undertaken to estimate the ARTI in different parts of India. The study in the rural areas of Kota, a subset of the 26 districts selected for the survey, is described in this article.

The survey in Kota district was conducted during July – October 2000. A total of 6264 children 1-9 years of age, residing in 64 rural clusters were registered into the study. The children were subjected to the standard tuberculin test using 1 TU PPD RT23 with Tween 80 procured from BCG laboratory, Guindy and the maximum transverse diameter of the induration was measured after about 72 hours. In all, 3157 children without BCG scar and 1520 with BCG scar were successfully test read. The prevalence of infection among children without BCG scar using the mirror image technique was estimated as 13.6% and the ARTI was computed at 2.6%. Using similar technique, the prevalence of infection among the entire study group-irrespective of BCG scar was estimated as 14.9% and the ARTI was computed at 2.8%. The result pertaining only to the rural areas were presented as the urban sample size of children without BCG scar was small.

The findings indicate a high rate of transmission of tuberculous infection in rural areas of Kota and emphasize the need for further strengthening of TB control measures. It is conjectured that the high prevalence of infection in Kota could perhaps be attributable to the low Human Development Index (HDI) of Rajasthan.

Key Words: *Tuberculin Test; Prevalence; Infection; Annual Risk.*

027: AVERAGE ANNUAL RISK OF TUBERCULOUS INFECTION IN INDIA

VK Chadha, P Kumar, PS Vaidyanathan, PS Jagannatha and KP Unnikrishnan: Int J Tuberc Lung Dis 2005, 9, 116-118.

As the majority of the tuberculin surveys in India had been confined to pockets in the southern region, a nation-wide study was undertaken between the years 2000 to 2003 to assess the epidemiological situation of TB in the country. For the purpose of the study, the country was stratified into four mutually exclusive zones, with the objective of estimating the average ARTI in each of the zones. This article disseminates the results of the average ARTI in the country.

The nation-wide tuberculin survey was conducted following uniform methodology in all the 4 zones. The survey was conducted among children 1-9 years of age residing in 1668 selected villages (rural clusters) and 645 urban blocks (urban clusters) in 26 districts of 19 states. The estimates of the prevalence of infection in the rural areas of the 4 zones were pooled together to obtain the national estimate for rural areas while those from the urban areas were pooled together to obtain the national estimate for urban areas. Rural and urban estimates of prevalence of infection at the national level were pooled to obtain the overall national estimate. The average prevalence of infection among children 1-9 years of age was estimated at 8.2% by the cut-off point method and 7.9% by the mirror image technique. The average ARTI for the country by both the methods was similar. The ARTI was computed as 1.5%, though it was higher in urban (2.2%) compared to rural areas (1.3%). The results call for further intensification of TB control activities, especially in urban areas, greater involvement of private practitioners and IEC for high-risk groups, to reduce the diagnostic and treatment delay thereby reducing the transmission of infection.

Keywords: *Infection; Tuberculin Test; Annual Risk; Control Program.*

028: ANNUAL RISK OF TUBERCULOUS INFECTION IN FOUR DEFINED ZONES OF INDIA – A COMPARITIVE PICTURE

VK Chadha, SP Agarwal, P Kumar, LS Chauhan and C Kollapan: Int J Tuberc Lung Dis 2005, 9, 569-575.

A nationwide tuberculin survey was undertaken during 2000 - 2003 as data on the epidemiological situation

of TB was lacking for most parts of India. The results of this study of epical proportions, provided for the first time vital information on the prevailing epidemiological situation of TB across the country. For the purpose of the survey, the country was stratified into 4 geographical zones - north, east, south and west - each having about a fourth of the country's population. The study was designed to obtain the average ARTI in each of the four zones. Though the results of the individual zones have been published earlier, the purpose of this article is to summarize the overall survey data to facilitate inter-zonal comparison.

The survey in each zone was conducted following uniform methodology. Using appropriate statistical techniques, 26 districts from the 4 zones were selected for the survey - 6 each from the north, south and west zones and eight from east zone. The survey was conducted in rural and urban clusters of the selected districts. From each cluster, 85 children, 1-9 years of age were registered for tuberculin testing with 1TU PPD RT23 with Tween 80 and the maximum transverse diameter of the reactions were read about 72 hours later.

Children with BCG scar were excluded from analysis. The data analyzed pertained to 85,218 children - 25,816 from north zone, 17,811 from south zone, 22,259 from west zone and 19,332 from east zone. The prevalence of infection was calculated both by the cut-off point method (Method I) and mirror image technique (Method II). The modes of tuberculin reactions attributable to tuberculous infection were observed at 20 mm in north, west and east zones and 19 mm in south zone. The anti-modes varied

from 14 to 16 mm in rural areas and 12 to 16 mm in urban areas of the four zones.

The ARTI computed from estimated prevalence was found to be lowest in south zone (Method-I: 1.1%, Method II - 1.0%). It was higher in east (1.3% by both Methods) and west zones (Method-I: 1.8%, Method-II: 1.6%) and highest in north zone (1.9% by both Methods). The proportion of infected children was found to be significantly higher in urban compared to rural areas in all the zones. The prevalence of infection estimated by Method I was also standardized by age, considering the study population in south zone as the standard population. The inter-zonal differences observed were almost similar to the non-standardized rates.

The average ARTI for the country was computed as 1.5% after pooling the data from the four zones. Therefore the ARTI in India is at least 15 times higher than the estimates of less than 0.1% in many developed countries. Applying Karel Styblo's parametric relationship between the ARTI and incidence of smear positive cases, it is expected that there would be 95, 55, 90 and 65 smear positive TB cases per 100,000 population for the north, south, west and east zones respectively. The high ARTI is largely due to the unsatisfactory performance of the erstwhile NTP. However, the introduction of the RNTCP in the country has raised hopes of controlling TB.

Key words: *Infection; Prevalence; Annual Risk; Tuberculin Test.*

Total: 28

SOCIOLOGY

SOCIOLOGY

029: SOCIOLOGICAL RESEARCH CONDUCTED IN THE FIELD OF TUBERCULOSIS IN INDIA

P Jagota: STC Newsletter 1999, 2, 5-15.

The application of social sciences to health problems is known as public health. The NTP evolved by the NTI Bangalore, included and regarded the sociologist as an equal member of the inter-disciplinary team of scientists, ensuring that the programme focused on people rather than on disease alone, making the NTP sociologically acceptable and epidemiologically effective. A large number of studies conducted in India have shed light on various epidemiological, sociological, bacteriological and organizational aspects of the programme. Human behaviour is a complex subject and it is important to learn about the sociological aspects of the disease. Extensive research carried out in India, over a period of time, on human behaviour related to TB, needs a wider dissemination among the TB workers globally. In this paper a comprehensive view of the research on the sociological aspects of TB conducted in India between 1956-1998 is presented under three headings.

1) Research on Human Suffering and Health Seeking Behaviour

These studies use two approaches to find out about the people's awareness, the first approach is based on the people's knowledge regarding the most important facts about TB, such as the cause of the disease, the mode of spread of infection and the frequency of the disease occurrence. This forms the basis for Health Education. The important observation was that the health behaviour of the people was independent of their level of knowledge of the disease and even when their level of knowledge was high, prevailing negative social attitudes were strong deterrents for people to take action for relief. The second approach depends on the physical suffering caused by the symptoms of TB. NTI has used this approach in its surveys. Interviews have been found to be simple, accurate and amenable tools in the hands of a trained investigator. The salient features of some of the studies, using these two approaches are presented in this paper. Community based findings have been corroborated with hospital outpatient findings. The conclusion drawn was, physical suffering due to the disease creates awareness among 95% of the patients in the community and 52% of them seek relief. There was no significant correlation between patient's

action taking and their knowledge, social status, education and other demographic factors. Studies have also shown that increasing knowledge by imparting health education has not changed the symptomatics into action taking group. Some studies suggest that distance, economic realities and quality of services offered by health providers are the over-riding factors for concern.

2) Research on Treatment and Behaviour of TB Patients

The low treatment efficiency achieved in the NTP has been attributed to default or non-compliance to treatment by patients. Earlier the patients alone were blamed for non completion of treatment and the words 'default' and 'non-compliance' were used to describe them, implying that the patients were subservient to the providers. Now it is recognized that non-patient factors, namely, organizational and administrative lacunae of TB services contribute to incomplete drug consumption. Factors found to affect the adherence and intervention to improve it are discussed in this section. A review of the adherence problem over a period of 3 decades showed the treatment completion rates ranged from 20% to 80% both with Standard and Short Course Regimens. The patient, the drug regimen and treatment organization were the factors which could influence the treatment completion rates. Having to travel long distances was a significant reason to stop treatment. Irregular and insufficient supply of drugs, lack of facilities for retrieval of patients, inappropriate drug regimens, incomplete addresses, advice of special diets, inconvenient working hours of the clinic and rude behaviour of the health staff also contribute to default. Findings of various studies on influence of motivation on patient behaviour and defaulter retrieval action and involvement of NGO's are also highlighted. The findings concluded that even after 30-35 years of NTP, the behaviour of the patients had not changed, but whenever quality of the services was good or improved, the utilization of the services by the patient also improved. Persistent symptoms are a cause for concern both in bacteriologically positive and negative cases. Treating patients by X-rays alone would lead to substantial over diagnosis and unnecessary treatment and also impose a strain on the meager resources. Hence the recommendation is that old TB patients should be given only symptomatic treatment unless they are smear or culture positive.

3) Genesis of Directly Observed Treatment Short Course (DOTS)

The concept of DOTS originated in India, through studies conducted at various institutions. A supervised intermittent regimen was developed by the TRC, Chennai and the efficacy of this supervised intermittent regimen was 94%. In another study, the twice weekly supervised regimen was also found to be robust. With the advent of the SCC, it was felt it would be possible to supervise drug intake during the intensive phase. According to one study, the treatment completion rates were high when the SCC drugs were administered under supervision during the intensive phase of treatment (with 1 SHRZ / 7 TH: treatment completion rate - 77.7%; with 2SHR/6 TH: the treatment completion rate - 77.5%). Another study revealed that when there was no supervision, the treatment rate was poor (33.2%). These findings indicate that it was possible to achieve high treatment completion rates if the drugs were administered under supervision. Thus the seed of DOTS were sown in India. After the introduction of DOTS

in India, further studies were conducted to find out other suitable DOT workers and the feasibility of using Dais, for DOTS. The RNTCP using DOTS as a strategy is being implemented in India since 1993 in a phased manner. There is an urgent need to address the issues concerned and facilitate prompt remedial action. Further it is also essential to study various sociological issues related to effective implementation of DOTS such as exploring the possibility of including the private practitioners, grass root level functionaries, chemists and other groups of people such as paan sellers, STD booth owners as DOT providers. TB control needs a long-term strategy, intense involvement of the health staff on mass scale would be sustainable only if problems related to the manpower are also investigated. Hence future sociological research should be focussed on various aspects related to the health services.

Key Words: *Sociological Research; India.*

Total: 1

OPERATIONS RESEARCH

a. CASE FINDING

030: VALIDITY OF CASE FINDING TOOLS IN A NATIONAL TUBERCULOSIS PROGRAMME

VH Balasangameshwara and AK Chakraborty: Tubercle and Lung Disease, 1993, 74, 52-58

For case-finding under the DTP in India, the recommended method is sputum smear microscopy of chest symptomatics attending the health institutions on their own. It is universally followed, with a slight variation in the procedure of initial screening of outpatient attendance respectively at the DTC and at PHIs. However it may be argued that smear microscopy of all patients with chest symptoms results in a high workload in terms of positivity rate for examinations done as well as for its comparatively lower predictive value of negativity. The authors felt that it would be interesting in this context to estimate validity of screening and diagnosis obtained under operational conditions.

The data available from some of the field surveys and from the DTP situation have been analysed for the above purpose. The validity of 3 methods of case finding at the DTC were assessed viz, subjecting all chest symptomatics to: (i) X-ray, (ii) sputum smear microscopy and (iii) chest symptomatics having positive x-rays to smear microscopy. The validity of these methods was measured against sputum culture, which was considered as the gold standard. The sensitivity, specificity and positive predictive value of X-rays were 87.7%, 95.9% and 52.3% - 72.2% (depending upon prevalence of cases among symptomatics) respectively. The sensitivity, specificity and positive predictive value of smear microscopy were 80.3%, 99.3% and 81.8% - 95.3% respectively. The sensitivity, specificity and positive predictive value of smear microscopy of those with positive X-rays were 75.3%, 99.8% and 92.2 - 99.9% respectively. Examined in the context of statistical reliability of tests, the methodology of prior X-ray screening adopted by the DTC for case finding for TB appears to be well founded. At the PHIs, the sensitivity, specificity and positive predictive value of sputum smear microscopy were 61.8%, 97.4% and 64.2% - 87% respectively. Thus, in contrast to the DTC, the need for X-ray screening at PHIs does not arise.

Keywords: *Casefinding; Casefinding Tools; Validity; NTP.*

031: CASE FINDING AND RELATED ISSUES IN TUBERCULOSIS

VK Chadha and DB Deshmukh: NTI Bulletin 1995, 31, 48-53.

Tuberculosis is one of the most widespread infections ever known to man. While people of all ages suffer, the heaviest toll occurs in those belonging to the productive age groups leading to adverse, social and economic consequences. Demographic changes and the epidemic of HIV are expected to increase the burden of TB. Early detection of cases by an efficient case finding programme followed by optimum treatment constitutes the most important control measure. The different case finding tools for the diagnoses of TB have been dealt in this article.

Case finding is defined as the well-organized and systematic effort to detect the largest possible number of cases in the community. The objective of case finding is to identify sources of infection in the community. Emphasis has been laid on case finding in rural areas as 75% of TB cases reside in these areas.

Culture examination of the sputum is considered as the gold standard for the diagnosis of TB but entails a tedious and expensive procedure. Radiological examination of the chest as the sole diagnostic tool for TB has the disadvantage of low specificity. Sputum microscopy is a highly specific diagnostic tool for TB. About 84% of smear positive cases presenting at PHIs can be detected by examination of 2 sputum specimens. Besides this, sputum microscopy is cheap. Chest symptoms as a screening tool has high sensitivity but has low specificity and hence cannot be used alone as a case finding tool. Newer diagnostic tools like BACTEC enable rapid detection of myco-bacterial growth in about 1-2 weeks. Tests based on PCR by amplification of a segment of DNA can detect even a few bacterial cells in a sputum specimen within a few days. However, these tests are very expensive and still in the process of standardization. Serological tests based on detection of mycobacterial antigens and antibodies have shown mixed results and find little application in a routine mycobacteriological laboratory. High operational costs and poor case yield prompted case finding by mass surveys to be abandoned. Examination of contacts can be recommended as a case finding method only if they have chest symptoms. Sputum camps, at best can be a periodic effort.

It is very important to control the quality of the technique used in case finding. There is need for development of a system for re-examination of sputum smears and the quality of microscopy and x-ray should be high. Delay in case finding is another important indicator of the quality of the TB control programme and tends to nullify the impact of treatment to a great extent. Case finding activities can be augmented through optimal utilization of multipurpose health workers. General practitioners should have adequate knowledge of the case finding tools for TB. NGOs should be involved in increasing the awareness of TB in the masses.

There are some issues in case finding that merit research like patient and community behaviour after development of symptoms, the development of more reliable, simple, rapid and inexpensive methods for identifying cases and a reliable tool for the diagnosis of smear negative pulmonary TB.

Key Words: *HIV; Case Finding; Culture Examination; Sputum Microscopy; Mycobacterium; Radiological Examination; DNA.*

032: CASE FINDING IN DISTRICT TUBERCULOSIS PROGRAMME, POTENTIAL AND PERFORMANCE

P Jagota, B Mahadev, N Srikantharamu, VH Balasangameshwara and TR Sreenivas: Indian J TB 1998, 45, 39-46.

In India the DTP is integrated with the general health services. The study conducted by the NTI in 1966 to estimate the "potential" of case finding by PHIs, estimated the proportion of chest symptomatics in the daily out patient attendance and the yield of TB cases. For more than 3 decades, these estimated expectations have formed the basis of programme monitoring, in respect of potential of case finding, work load and efficiency of performance of the participating PHIs of DTPs. Even the best performing PHIs have not achieved as per the expectations. Infact monitoring data has shown sputum positivity among chest symptomatics has declined from 12% in 1978 to 5% in 1988. Hence the objective of the present study was to investigate the potential and performance of case finding in a DTP spread over a period of one year, in terms of proportion of chest symptomatics among the self reporting new out patients in PHIs; the proportion of smear and

culture positive TB cases among the chest symptomatics and comparing the potential of case finding with the actual performance of PHIs.

In the study, patients were categorized into 3 categories depending upon the age, duration of cough and other symptoms. The term potential refers to the number of TB cases diagnosed during 1 year when all programme recommendations were followed by the PHIs, performance implies case finding efficiency actually achieved by the PHI staff in existing programme situation.

Potential and performance of case finding in DTP were studied in Tumkur District of Karnataka State from September 1991 to March 1993. For the potential study, a total of 32,810 outpatients were registered by NTI team. Of them, 21.4% were children below 10 years of age, who contributed only 0.5% to the total chest symptomatics and no case of TB. Among the 32,810 outpatients, as many as 944 (3.7%) were chest symptomatics, aged ≥ 10 years who were subjected to sputum examination by smear and culture. Among the 944 symptomatics, 86 (9.4%) were found positive by smear and 87 (9.5%) by culture.

The findings of the study suggest that it was not necessary to change the estimated potential of case finding in PHIs, thus validating the indices used for nation wide monitoring of DTPs, that is, 3.5% of the out patients are chest symptomatics and 10% are smear positive among them. The actual performance by PHIs in this study was only 14% of the potential.

Key Words: *Case Finding; Potential; Performance.*

033: CASE FINDING POLICY FOR NTP LEADING ARTICLE

P Jagota: Indian J TB 1998, 45, 3-7.

The NTP formulated in 1962 was integrated with the general health services. NTP as a system was ahead of its time in 1962. All other disease control programmes were vertical in their organizational structure.

The available option regarding the methodology of case finding were a) Mass miniature radiography to find X-ray abnormalities b) Sputum testing of X-ray abnormalities as well as chest symptomatics. It was demonstrated that mass radiographic examination of population may not discover more than 1/3rd of the sputum positive cases of TB despite the enormous efforts made and expenses incurred.

Case finding procedures adopted may vary in different kinds of health institutions in order to get optimum case yield from the different types of out patient attendance in them. Sputum smear method is most appropriate in PHIs because only 3.7% of out patients are chest symptomatics of whom around 10% are sputum smear positive.

DTC on the other hand, is a specialized unit where the chest symptomatics comprise 85% of out patients. The use of X-ray examination first at DTC was recommended under NTP as another screening tool to reduce the laboratory work load and thereby, improve smear positivity rate. The smear negative symptomatics referred by various PHIs were also attended to in the process. However it was observed that over diagnosis due to excessive use of X-ray was enormous and only 20% of patients diagnosed in the district were confirmed by sputum examination.

Availability of culture facilities at STC could help in case finding and surveillance of drug resistance. The case finding activities at DTCs and PHIs require monitoring and supervision by the STC. The article also has dwelled upon future prospects of TB control.

Key Words: *Case Finding Policy; Symptom Screening; Sputum Microscopy; Programme Manager; Supervision.*

034: MERITS AND DEMERITS OF CONVENTIONALLY USED DIAGNOSTIC TOOLS IN PULMONARY TUBERCULOSIS UNDER NATIONAL TUBERCULOSIS CONTROL PROGRAMME

B Mahadev: NTI Bulletin 1998, 34, 6-8.

Tuberculosis has been declared as a Global Emergency by WHO in 1993. TB takes a heavy toll in the community both in terms of morbidity and mortality. A decision has been taken by the Government of India, Central TB division to adopt the diagnostic and registration system of the RNTCP in preparation for transition to the revised strategy in the SCC districts of the country. This paper makes an attempt to highlight the merits and demerits of the various tools in the diagnosis of TB to create an awareness of the importance of diagnosing smear positive pulmonary TB and treating them effectively. Selection of chest symptomatics is an important screening tool for the diagnosis of TB. It is simple and widely applicable and helps to reduce work load of sputum examination. Indiscriminate symptom screening reduces the predictive

value of sputum smear microscopy. The diagnostic tools used for diagnosis of TB are 1) Sputum Microscopy 2) Chest X-ray 3) Tuberculin testing 4) Culture for TB bacilli

1. **Sputum Microscopy:** It is simple, highly specific, reliable and widely accepted, results are quickly available, cost effective, declares infectiousness of a patient and useful for follow up. The disadvantages are, it is less sensitive and cannot differentiate between live and dead bacilli.
2. **Chest X-ray:** It is a highly sensitive screening tool, but its specificity is low, etiology of abnormal shadows cannot be determined and it is difficult to assess the activity of the lesions and there are large inter and intra-reader variations.
3. **Tuberculin test:** It is used for clinical and epidemiological purposes. It is useful as a corroborative evidence in diagnosing childhood forms of TB and to carry out tuberculin surveys. This test needs to be interpreted with caution as BCG vaccination, infection with environmental mycobacteria and frequent tuberculin tests interfere with the interpretation of results.
4. **Culture for TB bacilli:** Considered to be the gold standard, it is a highly sensitive and specific tool and is used in epidemiological and drug resistance surveillance studies. Sputum culture examinations are expensive, time consuming and require highly skilled personnel. Hence sputum culture cannot be used as a routine diagnostic tool.

Hence sputum microscopy is the tool of choice, for the first line of investigation in the diagnosis of pulmonary TB. Selection of self reporting chest symptomatics and subjecting them to 3 sputum examinations should become part of the routine for diagnosis of TB. Newer diagnostic tools like PCR, ELISA, Gene Probe etc are still being evaluated.

Key Words: *Symptom Screening; Sputum Microscopy; Chest X-ray; Tuberculin Test; Culture.*

Total: 5

b. PROGRAMME DEVELOPMENT

035: DYNAMICS OF TREATMENT UNDER VARIOUS CHEMOTHERAPY SITUATIONS IN THE TUBERCULOSIS CONTROL PROGRAMME

P Jagota: NTI Bulletin 1995, 31, 1-6.

Domiciliary treatment and introduction of SCC are the crucial break throughs in the field of anti-TB treatment in the recent past. With the ambulatory system of drug administration, the concept of "organization" and "treatment delivery" came into existence. Introduction of SCC did not warrant a creation of new system for treatment delivery but rather an improvement in the existing treatment organization. It became vital to apply SCC in an efficient organizational framework. Introduction of SCC is a technical advancement with sociological and epidemiological gains. The advantages of SCC are summarized in the paper. However, important requirement of any regimen is the efficiency of treatment delivery. The distinction between efficiency and efficacy of the chemotherapy has been explicitly brought out in the paper. The latter largely depends on the treatment delivery system.

Hence NTI conducted studies on 'potential efficacy' which could be used to compare results of DTP units with wide range of conditions. The findings were: in a no intervention situation (natural dynamics) 27.8% became culture negative, 30.2% died and 42% remained culture positive at the end of 18 months. At the end of 5 years, 18% were still culture positive and 50% were dead. When treatment was given in accordance with guidelines of DTP at an urban DTC with SR regimen, at the end of 12 months irrespective of level of drug collection, 63% became culture negative, 10% died, 27% continued as culture positive. Five-year follow up results showed 59% culture negative, 30% dead and 11% culture positive. With the SCC regimen it was seen that at the end of treatment 90% became culture negative, none died and 10% were culture positive and at the end of two years 76.2% remained culture negative, 2.7% died and 21.1% were culture positive. The important finding being; compared to SR, SCC had lower fatality and nearly 20% improved negativity status on sputum examination, both at the end of treatment and follow up. In another study done in field conditions where only drug supply was assured, 66% were culture negative at the end of treatment, 13% died and 21% continued to be culture positive, the results were thus inferior to potential. Another retrospective study in the same district showed that the

gap between potential and performance with SR was wide while with SCC it was only 10%. When studies were conducted to find reasons for loss of efficacy, it was revealed that the unfavourable outcome was mainly due to poor compliance as majority (79.5%) on SR were lost from treatment compared to 30% on SCC. Computation of results showed patients on SR who were lost to treatment had outcome similar to a no intervention situation. SR and SCC regimens were comparable when treatments were completed, but SCC regimens had lower fatality and nearly 20% additional culture negativity. Results of patients lost during treatment with SCC were comparatively better than those lost during SR. More organizational efforts are required to ensure compliance in SR regimens. These results tilt the balance overwhelmingly in favor of SCC regimens as the regimen of choice for clinicians and for public health application. Other decisive factor for efficient treatment delivery system is availability of anti-TB drugs at all times, for which adequate funds are required. No new anti-TB drugs are in the pipeline, hence strengthening of the delivery system is the only way to get results from existing regimens.

In conclusion, organized treatment delivery is of paramount importance irrespective of the treatment regimen. When only a small proportion of patients in the community are put on SCC, its epidemiological impact could be minimal, even with high cure rates.

Key Words: *Efficiency; Efficacy; Natural Dynamics; SR, SCC Regimen.*

036: PERSISTENT CHEST SYMPTOMS IN SMEAR POSITIVE PULMONARY TUBERCULOSIS PATIENTS TREATED WITH STANDARD AND SHORT COURSE CHEMOTHERAPY REGIMENS UNDER A DISTRICT TUBERCULOSIS PROGRAMME—A FIVE YEAR FOLLOW -UP

VH Balasangameshwara, P Jagota and R Channabasavaiah; Indian J TB 1996, 43, 143-150.

An earlier study on the outcome of chemotherapy in smear positive pulmonary TB cases five years after diagnosis had collected information regarding persistent chest symptoms and subsequent treatment taken by patients. This study reported that 42.4% of patients on SR and 22.1% of patients on SCC were still having chest symptoms. In this report the SR and SCC groups were analyzed with

the aim of identifying differences in the proportion of patients having persistent chest symptoms, their culture results at the end of five years, subsequent treatment taken and levels of adherence during primary treatment.

Smear positive pulmonary TB patients aged 5 years and above on treatment with SR and SCC regimens during 1985 at LWSTC, residing within Bangalore city limits formed the study material for the main study. The data on the treatment cards were re-analyzed for levels of primary treatment. Using the addresses, the patients were traced 5 years after the primary treatment and history regarding subsequent treatment was collected. Two sputum samples were collected and subjected for microscopy and culture. A social worker from NTI independently collected information about presence of persisting symptoms from the contacted patients.

Out of the 1227 eligible patients registered at LWSTC in 1985, only 302 were available for this analysis. Of the 302 patients, 52 were sputum culture positive, and 110 patients had persistent chest symptoms. Of 216 cases who had received subsequent treatment, information on anti-TB treatment could not be elicited in 77. Among the remaining 139 contacted patients, 30.2%, 59.7% and 10.1% had received SR, SCC, and SR+SCC respectively. Chest symptoms persisted more among those found culture positive compared to those having negative culture. Majority (about 80%) of such patients who had availed government health facilities initially, continued to take anti-TB treatment for persistent symptoms from government facilities. Effective treatment with SR regimens had reduced the proportion of patients with persistent chest symptoms and the situation was still better with SCC. Despite the presence of persistent chest symptoms in about 1/3rd of the subsequent culture positive patients, attending physicians did not examine their sputum again for AFB and they did not receive subsequent anti-TB treatment. However, subsequent anti-TB treatment did not reduce the proportion of patients having persistent chest symptoms. The practice of prescribing specific subsequent anti-TB treatment, therefore, should be based on the result of smear examination and not on symptoms in treated cases.

Key Words: *Persistence; Symptoms; SR; SCC; Sputum Examination.*

037: IMPROVING TREATMENT COMPLIANCE BY OBSERVING DIFFERENCES IN TREATMENT IRREGULARITY.

P Jagota, TR Sreenivas and N Parimala: Indian J TB 1996, 43, 75-80.

Unsupervised domiciliary chemotherapy has been the mainstay of TB programmes of many developing countries. However, it was attended with widespread non-compliance. Default and loss of patients to treatment were 2 serious impediments to the success of domiciliary treatment. The aim of this retrospective study was to identify the risk group for default among patients treated at the DTC and 6 PHIs, in Kolar district of Karnataka state.

The material for this paper was derived from a study conducted from April 1988 to June 1989, for results of treatment with an SCC regimen at the DTC and 6 PHIs of Kolar district of Karnataka state. Five hundred and eighty four consecutively diagnosed smear positive patients, from these centres, aged more than 15 years and who were willing to accept the SCC regimen (2EHRZ/ 6 TH) formed the subjects for the study. Uninterrupted drug supply was ensured and defaulter actions were taken as per the NTP guidelines. These defaulter actions were not supervised or ensured by the research team from NTI.

From a total of 382 patients, 10 did not default (failure to collect drugs, till evening of the due date) even once during the entire period of the treatment. Of the remaining 372 patients, 231 defaulted for the first time in the first month of the treatment (First Timers) and 141 defaulted for the first time after first month of treatment (Others). Among the First Timers 83% were lost by the end of treatment, while it was 61% in Others. The treatment completion rate was 25% in First Timers and 59 % in Others. Completed treatment was defined as patients, who had taken 75% or more of the prescribed treatment in both the phases of SCC regimen. The bacteriological conversion at the end of treatment was 58.5% among First Timers and 76.9% among Others.

Thus, First timers could become predictors of default. They constitute the important target group for focussing intensive efforts to improve case holding, which is expected to improve to the extent of 30%.

Key words: *First Timers; Defaulter; Compliance, Non-compliance.*

038: PROFILE OF DAIS AND ANGAWADI WORKERS FOR THEIR POSSIBLE UTILISATION AS DRUG DISTRIBUTORS IN NATIONAL TUBERCULOSIS PROGRAMME

Sophia Vijay, TR Sreenivas, N Parimala and S Prabhakar: NTI Bulletin 1996, 32, 39-48.

Non-adherence to treatment has been a persistent and major problem in the NTP. Under the NTP, only 33% of cases are being diagnosed and only 40-50% of diagnosed cases are satisfactorily completing treatment. The introduction of SCC has not changed matters. Supervised drug administration nearer to patient's home seems to be a plausible solution to achieve the desired compliance and cure rates. For supervised therapy, grass root level workers within the community need to be identified. In this study, an attempt has been made to assess the suitability of TBA/Dai and AW for drug distribution. The objectives of this study was to obtain: 1) The profile of Dais and AWs indicating their suitability for involvement in the NTP and 2) The profile of villages to assess the influence of infrastructural development on the institution of Dais and AWs.

This study was carried out in Mandya district of Karnataka state. Villages with less than 5000 population numbering 1348 representing the rural component, constituted the study area and 67 villages were selected for the study. The list of trained Dais were obtained from the respective PHC's. Village profiles of the selected villages were obtained, trained Dais both registered and unregistered were identified and they were interviewed using semi-structured interview schedules at their homes by SI. Similarly, the AWs were also contacted and interviewed at the Anganawadi Centres.

The selected and non-selected villages were homogenous in terms of demographic characteristics, but literacy rates were lower in the villages selected for the study. Twenty-two out of the 67 (32%) villages had no trained Dais. Of the expected 87 trained dais only 45 were satisfactorily interviewed. Four of these 45 dais were not practicing, hence excluded from further analysis. Only 41 Dais remained for analysis. There were no AW's in 29 of the sample villages. In the remaining 38 villages, only 40 of the 47 AWs were satisfactorily interviewed. The demographic data of the villages revealed a heterogeneity with extreme observations. To maintain homogeneity, the villages were divided into clusters I, II and III. Cluster II and III villages had better infrastructure in terms of facilities

for education, health and presence of industries. There were 1.3 trained Dais per village in cluster III and only 0.5 dais in cluster I. Similarly there were 1.5 AWs per village in cluster III and 0.4 per village in cluster I. Seventy eight percent of the Dais were 40 years and above whereas 87.5% of the AWs were below 35 years. More than 50% of the Dais and AWs belonged to other backward classes and scheduled castes. The AWs were more academically qualified. Eventhough majority of Dais were illiterate 61% of Dais were able to identify particular number of box correctly. Sixty three percent of Dais and 37% of AWs were engaged in other kind of occupation like agriculture, tailoring etc. 38.5% of AWs did not stay in the village of their work. Fifty one percent of Dais did not participate in any of the national health programmes while 75-82% of AWs participated. General knowledge about the diseases in the community of both Dais and AWs was poor, but their attitude of talking to visiting TB patients was very favourable. When suitability for involvement in DOTS was explored, 98% of AWs and 53% among Dais were found to be suitable. .

The advanced age of Dais might give them a better acceptance by the community, but may render them less efficient to adopt a new role and high level of illiteracy may come in the way of maintaining records. The Dais, as they were staying in the same villages were more accessible than AWs. The caste factor in respect of Dais for DOTS cannot be predicted, but would not come in the way of AWs as they are representatives of government scheme and they have better social standing in the community. To use Dais and AWs, the programme needs simplification, adequate training and motivation. More practical exploration in a well-planned field trial is required.

Key Words: *Dais; Anganwadi Workers; Drug Distributors Profile.*

039: AN ALTERNATIVE METHOD OF PROVIDING SUPERVISED SHORT COURSE CHEMOTHERAPY IN DISTRICT TUBERCULOSIS PROGRAMME

P Jagota, VH Balasangameshwara, MJ Jayalakshmi and MM Islam: Indian J TB 1997, 44, 73-77.

Non-adherence to prescribed anti-TB treatment is a major obstacle in TB control. Various studies have shown the treatment completion rates in SCC regimens to be in the range of 33% - 55%. Poor treatment adherence remains a problem despite having SCC regimens of high efficacy.

The DOTS which has now been proposed under the RNTCP is yet to take-off. A need was felt to find an alternative drug distribution method for supervised drug administration, which is convenient and acceptable to patients in terms of distance and time. The TBA (Dai) is invariably available in each village, hence a study was conducted by the NTI to assess the utility of Dais for supervised drug administration to the patients.

The objectives of the study were to compare the treatment completion and the cure rates, as assessed by sputum microscopy, when drug distribution was undertaken by Dais, with that following the usual DTP procedure. The operational efficiency of drug supply from the PHI by the 2 methods was also studied.

The study was conducted in Kolar and Tumkur districts of Karnataka from September 1994 to March 1995. A total of 47 PHIs from 8 taluks under Dai method and 59 PHIs from 7 taluks under PHI method were selected for the study. Smear positive pulmonary TB patients diagnosed at the PHIs with no history of previous treatment with anti-TB drugs and residing within the study area were eligible for the intake. In the Dai method, the drugs for 10 days were sent to the Dai through the Health Worker. In the PHI method the drugs were issued to patients on a fortnightly basis as per DTP procedure.

A total of 617 patients were observed-332 in the Dai method (of the 332 patients, 187 were initiated on treatment by Dais and 145 by providers who were considered to be equivalent to Dais) and 285 in the PHI method. About 68% of patients in the Dai method and 33% in the PHI method took more than 75% of SCC treatment in both intensive and continuation phases. The outcome in terms of smear negativity at the end of treatment period was 86.9% and 72.2% respectively. There were 17 (5.12%) deaths in the Dai method and 16 (5.61%) in the PHI method. Treatment completion and cure rates were significantly higher in the Dai method.

It appears possible to utilize the services of Dais for distribution of drugs to TB patients with a suitable SCC regimen. Level of compliance as well as favourable response to treatment were significantly higher in the Dai method in comparison to PHI method. The patients, whose treatment was supervised by drug distributors other than the Dais, also achieved better results in comparison to the PHI method. Deaths in the 2 groups were low and similar.

Key Words: *Alternate Method; Supervised SCC; Dai; Dai Method; PHI Method; Treatment Completion Pattern; Cure Rate.*

040: PREVENTION AND TREATMENT OF TUBERCULOSIS AND ITS TECHNOLOGY REQUIREMENTS

P Jagota: Proceedings of the Seminar on Technology Management in Health Care Systems held at DEBEL Bangalore, from 18-19 July 1998, 88-96.

The National Sample Survey (NSS) conducted in 1955-58 suggested the prevalence of bacillary pulmonary TB was 0.4% and radiologically active abacillary cases was 1.6%. It also suggested that the disease was equally distributed in rural and urban areas and as majority of our population lived in rural areas, the problem was more in the rural areas than originally thought. At present it is estimated that 14 million persons suffer from pulmonary TB and of these 3-3.5 million are thought to be infectious bacillary cases. About 1 million new bacillary cases are added each year while 0.5 million die of TB every year.

The discovery of anti-TB drugs revolutionized the management of TB, making it a completely curable disease. Standard regimens of 18 months duration and SCC Regimens of 6-8 months are the ones, which are commonly used today. The preventive measures available are BCG and chemoprophylaxis but both have not lived up to expectations in preventing the disease. The best prevention at present is cutting the chain of transmission of tuberculous infection through cure of bacillary cases. Making accurate diagnosis, using established treatment regimens, ensuring compliance and cure through a nation wide TB programme is considered one of the most cost effective health interventions. Based on the findings of the NSS, the NTI was established in Bangalore with the responsibility of formulating the TB control programme. Studies conducted at the NTI lead to evolving of a programme with the district as its pivot. This was known as the DTP. After being field tested at Ananthpur, in Andhra Pradesh, the programme was adopted in a phased manner throughout the country. The objective of the programme was to detect maximum number of TB patients in the community and to treat them effectively through defined strategies. The DTP functions from the DTC, situated at the district head quarters. There are five key personnel at the DTC to run the programme. The personnel are trained to supervise the PHIs as the programme is integrated with the general health services.

Though the NTP was started in 1962 it did not achieve the desired results. Keeping in mind, the changing

scenario due to the dual epidemic of TB and HIV, sweeping the world, the GOI reviewed the programme in 1992 and the RNTCP was formulated to be implemented all over the country in a phased manner. The RNTCP emphasises on achieving cure rate of at least 85% and augmenting case finding to detect at least 70% of the estimated cases using the DOTS strategy.

Technology related to diagnosis and treatment of TB has not advanced to the desired levels due to lack of basic research. Apart from X-ray and isolation of *M. Tuberculosis*, no standard tool for diagnosis has been invented or discovered. No single-drug regimen has been found to be effective, only multi-drug combinations needing long duration of use are available. After 1967, no new potent drug has been discovered. Immuno-modulation and Immuno-therapy with *M. vaccae* are the new concepts being studied and showing some promise for the future. Newer diagnostic techniques include PCR, immunoassay for detection of antigen and gas liquid chromatography.

Poor implementation of control strategies and lack of socioeconomic progress, in the developing countries lead to failure in achieving a decline in the TB situation. Improper use of drugs has further worsened the situation. The RNTCP has been implemented with financial assistance from the World Bank. Till such time new drugs are discovered or cheaper, quicker and reliable diagnostic tools are found, sustained and untiring efforts to implement the RNTCP, alone would make TB control a reality.

Key Words: *Prevention; Treatment; Technology Requirements.*

041: FOLLOW UP OF PULMONARY TUBERCULOSIS PATIENTS TREATED WITH SHORT COURSE CHEMOTHERAPY THROUGH TRADITIONAL BIRTH ATTENDANTS (DAIS)

P Jagota, Sujatha Chandrashekar and G Sumathi: Indian J TB 1998, 45, 89-93.

Presently, for control of TB, emphasis is being given for improving treatment compliance and cure rates by using DOTS. Depending on local conditions, the DOT provider can differ from place to place. One such provider identified was the TBA (Dai). In 2 districts of Karnataka, the efficiency of drug administration through Dais was recently studied. In this study newly diagnosed 332 smear positive patients were given DOT by Dais and another 285 smear positive patients formed the control group who received

treatment through the health system as per programme guidelines. Forty seven PHIs from Kolar and Tumkur districts of Karnataka formed the study area. The treatment completion rates were 68% and cure rate was 86.9% using Dais and in the control group the treatment completion rate was 33% and cure rate was 72%. The objective of the present study was to find out the status of these smear positive pulmonary TB patients two years after their treatment in terms of cure, relapse, death, chronic failure and persistence of chest symptoms with action taken. The definitions of these terms are as under -

Cure: Sputum negative by culture at the time of follow up irrespective of sputum status at the end of 6 months' treatment.

Relapse Free Cure: Sputum culture negative both at the end of treatment and at the end of follow up.

Relapse: Sputum smear negative at the end of treatment but positive at the time of follow up.

Chronic failure: Sputum positive both at the end of treatment as well as at the time of follow up.

Of the 332 patients who had been treated by Dais, 17 were dead and 27 had migrated, after 6 months of treatment initiation. Two hundred and Eighty Eight (118 from Kolar and 170 from Tumkur) were eligible for follow up and formed the study population. This follow up study was carried out from January 1996 to June 1996. The patients were contacted at their residence and interviewed using a questionnaire for history of symptoms and duration, details of treatment taken if any, results of sputum/ X-ray if done and if already dead, the time and cause of death was ascertained from relatives. From these patients, two sputum specimens, 1 spot and 1 overnight was collected and subjected to direct smear, culture and sensitivity tests.

Of the 288 eligible patients at the time of follow up after 2 years, information on 283 could be obtained, of these about 78% had taken more than 75% of drugs during the intensive and continuation phases. At the end of two years, 79.6% had remained relapse free, 7.42% had relapsed and 3.53% remained sputum positive and 8.5% had died. Relapse rate in Kolar was higher than in Tumkur. Death rate in Kolar was significantly higher than in Tumkur. Of the 251 patients interviewed, 131 continued to have chest symptoms 2 years after treatment. Thirty one patients were found to be positive on culture and 24 of them were chest symptomatics. The remaining 7 sputum positive cases were either having non-suggestive symptoms or no symptoms. Even after 24 months 80% relapse free cure was achieved

by giving DOTS using Dais as DOT providers, thus indicating that Dais can be successfully used in giving supervised treatment. The overall mortality rates were also much lower as also relapses and failures. Half the patients still complained of persistent chest symptoms at the end of 2 years inspite of adequate completion of treatment. But 80% of these patients did not have bacteriologically active disease but only sequelae which would persist throughout life. More operational studies are required to establish the feasibility of utilizing Dais for the RNTCP.

Key Words: *DOTS; Dai; Follow up; Cure; Relapse; Failure; Death.*

042: FATE OF PULMONARY TUBERCULOSIS PATIENTS DIAGNOSED IN A PREVALENCE SURVEY- A SOCIO EPIDEMIOLOGICAL FOLLOW UP AFTER 5 YEARS

Sophia Vijay, MS Krishnamurthy and N Srikantaramu:
Indian J TB 1998, 45, 199-205.

Knowledge about the epidemiological trend of pulmonary TB is enriched by prevalence surveys done from time to time in randomly selected population. The study of fate of bacteriological cases diagnosed during such surveys over a period would help to understand the disease dynamics in an area. Before the implementation of NTP, a longitudinal survey was conducted (1961-66) in rural areas and NTI had also reported on the 5 year fate of cases discovered in this survey which reflects the natural dynamics of the disease. The present study was carried out in an adjacent peri-urban area where NTP was implemented in early 70's. Comparison of 5-year fate of cases in these studies can provide information on the impact of the anti-TB measures in the study area. Keeping in view these factors, a socio-epidemiological study was undertaken after an interval of 5 years with the objective to study fate of 'cases' and 'suspects' in terms of disease status, deaths, their health seeking behavior between surveys and the current symptom status.

A case was defined as person having radiological abnormality and/or cardinal symptoms of TB for 2 weeks or more and sputum culture positive for *M. tuberculosis*, while a suspect was a person whose X-ray was interpreted as active TB by two readers and whose sputum culture is negative for *M. tuberculosis*.

NTP was implemented in the survey area for more than 20 years. Survey I was carried out between August

1986 to October 1989 in 60 randomly selected villages located at radius of 19-24 km from the centre of Bangalore city. The total population registered was 56,293. Of the total population 35,653 were ³ 15 years and eligible for the study. Of the eligibles, 30,141 persons were available and interviewed to obtain information regarding cardinal symptoms of pulmonary TB. From those reporting chest symptoms for more than 15 days spot sputum samples were collected and subjected to smear microscopy, culture and sensitivity examinations for *M. tuberculosis*. The entire eligible population was also subjected to MMR irrespective of their symptom status. From the 30,141 persons examined, 86 cases and 341 suspects were diagnosed in Survey I. These 86 cases and 341 suspects formed the study group for Survey II after an average interval of 5 years when they were subjected to MMR and one spot sputum examination. SI using pre-designed schedules, containing all details of cases and suspects, contacted the available cases/suspects at their residence and gathered information on current symptoms, sources approached for treatment and details of treatment received between the 2 surveys. For cases/suspects who were reported dead between surveys, probable cause of death was ascertained from a responsible household member following the procedure adopted by Census of India.

Out of the 86 cases from Survey I, only 60 (69.8%) cases could be studied in Survey II. Among these 35 (58.3%) cases were reported dead, 18 (30%) culture negative and 7 (11.7%) were culture positive after an interval of about 5 years. Among the 341 suspects in Survey I, only 240 (70.4%) suspects could be studied at Survey II. Among these 73 (30.4%) were dead, 159 (66.3%) remained culture negative and 8 (3.3%) became culture positive. The age standardized proportion of deaths among suspects (28.5%) was significantly lower than among cases (58.7%) ($P < 0.1$). Deaths in 14 cases (40%) and 25 suspects (34.2%) could be attributed to TB as inferred by SI's after interview, but valid conclusions could not be drawn. Suspects epidemiologically proved to be a low priority group as the breakdown to culture positivity as observed among them over 5 years was as low as 3.3%. It was similar to the findings in the non intervention area of a longitudinal survey.

Sociological enquiry revealed that cardinal symptoms of TB persisted even after 5 years in 65% of cases and 55% of suspects. Action taking behavior indicated that more than half the patients reported to government health centres for remedial measures. Even

after three decades, the pattern of health seeking behavior of patients in these areas has remained the same inspite of the private sector having expanded by leaps and bounds.

The status of cases in terms of death and bacteriological conversion after five years in the present study did not show significant difference with the corresponding age standardized rates of the longitudinal study. The observed fate of suspects in these two studies also failed to show significant difference. The findings suggest that the same dynamics of TB as observed under the non-intervention situation, prevailed in the study area despite the latter being under the cover of NTP for more than 2 decades.

Key Words: *Survey, Cases; Suspects; Socio Epidemiological Follow-up.*

043: TREATMENT DYNAMICS AND PROFILE OF TUBERCULOSIS PATIENTS UNDER THE DISTRICT TUBERCULOSIS PROGRAMME – A PROSPECTIVE COHORT STUDY

Sophia Vijay, VH Balasangameshwara and N Srikantharamu: Indian J TB 1999, 46, 239- 249.

Ensuring adherence to treatment has long been acknowledged as the weakest component of the NTP in India. Several studies have attempted to investigate the factors responsible for non-adherence to treatment. Many of these studies were retrospective in nature, seeking information through interviews at the end of treatment. The treatment behaviour of patients is complex and several factors may shape the behaviour till the final outcome. A cohort of newly diagnosed smear positive cases initiated on SCC in a DTP was followed up prospectively to study the dynamics of treatment behaviour from diagnosis till the final treatment outcome. The specific objectives were to study: Treatment outcome including persistence of symptoms and bacteriological status; Profile of adherent and non adherent patients to identify the probable causes of non-adherence; Reasons for stopping treatment by patients "lost" to treatment.

This study was taken up in Kolar district of Karnataka State as it represents an average Indian district in terms of area and demographic characteristics, a reasonably good case-finding activity and for operational convenience. The DTC and all the 8 PHIs offering SCC to the new smear positive patients were selected. The intake period was prefixed as January to September 1997

to get at least 200 new smear positive patients. The study cohort consisted of all smear positive patients aged ≥ 15 years, initiated on SCC regimen $R_A: 2\text{ HRZE}/6\text{T(E)H}$ from 1st January 1997 onwards in all the selected centres. They were followed up prospectively throughout the treatment period. Information regarding new smear positive patients diagnosed and initiated on treatment was collected through scrutiny of the centres records every month. Initial data was collected by administration of a pre-tested structured schedule through patient interview by an experienced SI at the patient's residence. A final interview was taken immediately after completion of the prescribed treatment period, irrespective of their treatment adherence status. The patients registered were expected to make a total of 10 drug collections from their respective treatment centres, as per the DTP guidelines. Patients who made 8 or more drug collections without interruption of more than 1 month within the prescribed duration of treatment were regarded as having 'Completed Treatment'. Patients interrupting treatment for more than 1 month and making less than 8 drug collections were regarded as 'lost'. Treatment taken elsewhere other than the initiating centre by patients who are 'lost' were regarded as 'Subsequent Treatment'.

During the intake period, 279 new smear patients were diagnosed in the 9 centres. Final treatment outcome could be ascertained for 224 patients. Of these, 120 (53.6%) "completed treatment", 68 (30.4%) were "lost" to treatment while 29 (12.9%) were reported "dead" and 7 (3.1%) had "migrated" outside the district during the treatment period. The cure rate of 47.3% for the cohort was unacceptably low compared to the desired cure rate of 85% emphasized by the WHO. The high proportions of "lost and "dead" were the major contributing factors for the low cure rate. Persistence of cough at the end of treatment was significantly more among lost patients compared to the completed group. This could be a factor for patients to stop treatment as "no improvement in health" was stated by 11 lost patients as the reason for stopping the treatment. Premature stoppage of treatment could have also resulted in the persistence of symptoms. The general profile of the patients, related to socio-economic, demographic, literacy and employment details did not differ significantly between the two subgroups. However, the treatment related factors like distance from health centre, knowledge of treatment duration, advice on treatment given after diagnosis, payments made to staff and for tonics were significantly more among patients lost to treatment. Raising of money to meet the expenditure, particularly through selling of valuables too was proportionately more among lost patients.

Defaulter retrieval action was not taken for more than 85% of all eligibles, both among completed and lost groups. Defaulter retrieval action was not taken even at the DTC level, inspite of the presence of specialized staff leading to the doubt as to who is the actual defaulter, the patient or the provider? Even with the lack of defaulter retrieval action, half of the patients had completed their treatment satisfactorily. Corrective actions like increasing the number of PHIs put under SCC, decentralization of treatment activity by referral to nearest centre, proper patient-provider interaction and strict adherence to the recommended treatment policy of providing free services are immediately required. Effective supervision by the state and district health authorities would go a long way in sustaining the corrective actions enforced.

Key Words: *Compliance; Cohort Study; Case Holding.*

044: RE-TREATMENT OUTCOME OF SMEAR POSITIVE TUBERCULOSIS CASES UNDER DOTS IN BANGALORE CITY

Sophia Vijay, VH Balasangameshwara, PS Jagannatha, VN Saroja, B Shivashankar and P Jagota: Indian J TB 2002, 49, 195-204.

The NTP till 1993 was offering largely un-supervised SCC regimens and the treatment completion rates were far below expectations. Haphazard use of Rifampicin from mid 80's onwards has led to increasing proportions of MDR-TB. Treatment of resistance cases has posed a therapeutic dilemma to developing countries with scarce resources. The RNTCP adopting the DOTS strategy was implemented in India from 1993 and has been scaled up rapidly since mid-1998. Based on the diagnostic algorithm and history of previous TB treatment, the cases are classified as "New" and "Re-treatment". The re-treatment cases are put on Cat-II regimen and comprise smear positive 'Failures', 'Relapses', 'Treatment after Default' (TAD) and 'Others'. The question often posed by clinicians is regarding effectiveness of Cat II regimen for re-treatment cases, especially those with MDR-TB. The data to address this question convincingly with the support of pre-treatment drug susceptibility profile are lacking.

A prospective study was undertaken in the RNTCP centers of BMP in a cohort of 226 smear positive re-treatment patients residing within the BMP limits initiated on Cat II regimen under DOTS from April 1999 to

September 2001. The cohort was followed up prospectively till treatment outcome. The objective of the study was to assess the treatment outcome with pre and post-treatment drug susceptibility profile of smear and culture positive re-treatment patients treated with Cat II regimen. The cohort was interviewed at the initiation and end of treatment using a pre-tested semi-structured questionnaire to elicit details regarding past and present treatment. Two sputum samples were also collected from the study cohort for microscopy, culture and drug susceptibility.

More than half of the study group (60%) were initially susceptible to all the regimen drugs. MDR-TB among the cohort was 12.8%. Treatment after default cases constituted bulk of the cohort (65.5%) and 'Defaults' among them were high (52.7%). The overall favorable treatment outcome in the cohort was only 39.8% as a result of high defaults (43.8%). However, favorable outcome among those completing the prescribed duration of treatment was 75% irrespective of pre-treatment drug susceptibility status. In addition, emergence of drug resistance, especially to Rifampicin was negligible (1.8%) during current treatment despite the high default rate suggesting effectiveness of Cat II regimen. Favorable response among pre-treatment MDR cases was low (17.2%) and remained so even after excluding defaults (22.7%).

The study underscores the importance of treatment adherence for achieving success. The focus of treating the cohort should have been on prompt defaulter retrieval, especially of patients belonging initially to the type 'Treatment after Default', who were potential defaulters. The low treatment efficiency in MDR cases makes it prudent to prevent development of MDR during primary treatment by strict adherence to DOTS, thereby making failed cases more amenable for re-treatment with Cat II regimen.

Key Words: *Re-treatment; Pulmonary TB; Cat II Regimen; Drug Resistance; Treatment Outcome.*

045. DEFAULTS AMONG TUBERCULOSIS PATIENTS TREATED UNDER DOTS IN BANGALORE CITY - A SEARCH FOR SOLUTION

Sophia Vijay, VH Balasangameshwara, PS Jagannatha, VN Saroja, P Kumar: Indian J TB, 2003, 50, 185-195

Defaulting from treatment has been one of the major obstacles and a challenge for TB control programs. To ensure treatment adherence the emphasis is now on Directly

observed treatment (DOT). The proportions of reported deaths, transferred out, failures have been persistently low. Hence, achieving the desired cure rate now depends on minimizing the rate of default.

A retrospective analysis of defaulted patients of a cohort of 264 new (CAT I) and 219 retreatment (CAT II) bacteriologically positive patients treated under DOTS from March 1999 to September 2000 was undertaken with the following objectives:

1. To identify socio-demographic and treatment related risk factors predictive of default with DOT
2. To study treatment regularity and final bacteriological profile of defaulted patients.

The study was conducted in urban setup of Bangalore Mahanagara Palike where Revised National Tuberculosis Control Programme was implemented in late 1998

Data collection was through review of records and patient interviews at treatment initiation and at treatment outcome using pre-tested semi-structured interview schedules.

Defaults were 25% and 45% in CAT I and CAT II respectively. The predictive factors associated with default identified through multivariate logistic regression were male (Adjusted Odds Ratio (AOR) =2.49(1.10-6.18)-CAT I, 2.78(1.15-6.7)-Cat II) and Alcoholic (AOR=6.38 (3.25-12.5)-CAT I, 3.93 (2.1-7.5)-Cat II). In addition, patients having poor knowledge of TB (AOR=3.06(1.24-7.54)-Cat II) and those returning for treatment after default (AOR=2.55(1.31-4.94)-Cat II) were predictors of default among re-treatment patients. Majority (CAT I =65.7%, CAT II =71%) of the patients defaulted in the Intensive Phase particularly after the 12th dose. More than half of the defaulted patients remained bacteriological positive at the end of treatment period.

The predictive risk factors of default with DOT in an urban setting are males and alcoholics. Those returning for treatment after default and having poor knowledge of disease are additional risk factors among re-treatment patients. Devoting attention to those at potential risk of defaults from the initiation of treatment with close supervision and repeated counseling would be a major input to minimize defaults and achieve desired goal of RNTCP.

Key Words: *Default; DOTS; TB Patients*

046: INITIAL DRUG RESISTANCE AMONG TUBERCULOSIS PATIENTS UNDER DOTS PROGRAMME IN BANGALORE CITY

Sophia Vijay, VH Balasangameshwara, PS Jagannatha and P Kumar: Indian J TB 2004, 51, 17-21.

The level of IDR and its trend is a sensitive indicator of the TB control programme efficiency and is an indirect reflection of the quality of TB control services in the area. Studies from some parts of India have reported an increase in the level of IDR to INH and Rifampicin. There is paucity of information on age specific pattern of IDR from India. Frequency of drug resistance in the younger age group provides a precise evaluation of the current situation. The published data from Bangalore (1985-86) pertaining to patients under the NTP reported an IDR of 20.6% to any drug. Subsequently, the RNTCP with DOTS strategy to achieve high cure rates was implemented in the area in late 1998. The present study was undertaken in BMP in a cohort of 324 new smear positive patients initiated on Cat-I regimen under RNTCP between April to December 1999, to study the pattern of IDR among them. As the study was undertaken soon after the implementation of RNTCP in the area, the results would serve as a baseline to assess the subsequent impact of the DOTS strategy on the level of IDR.

Two pre-treatment sputum samples were collected from patients and subjected to microscopy, culture and susceptibility testing at the NTI, Bangalore. The susceptibility testing was done by economic version of proportion method, as per IUATLD guidelines. Information regarding previous treatment was elicited using a pre-tested semi-structured schedule based on the WHO questionnaire for IDR surveillance and scrutiny of available records.

Among the 271 correctly categorized new patients, 27.7% were resistant to one or more drugs. The resistance to streptomycin was highest (22.5%) followed by INH (13.7%) and MDR was 2.2%. The age specific resistance was highest in <25 years and declined significantly in the higher age groups, being lowest (17.7%) in ≥45 years. Effective RNTCP implementation is expected to show declining trends in the IDR, particularly in the younger age group during subsequent surveys.

Key Words: *Tuberculosis; Initial Drug Resistance; DOTS.*

047: TREATMENT OUTCOME AND TWO AND HALF YEARS FOLLOW-UP STATUS OF NEW SMEAR POSITIVE PATIENTS TREATED UNDER RNTCP

Sophia Vijay, VH Balasangameshwara, PS Jagannatha, VN Saroja and P Kumar: Indian J TB 2004, 51, 199-208.

This study was undertaken in the city of Bangalore to evaluate the treatment outcome of new smear positive patients supported with pre and post-treatment bacteriological profile and also to assess their bacteriological and clinical status two and half years after initiation of treatment.

It was a prospective cohort study among 271 new smear and culture positive patients initiated on Cat I regimen between April to December 1999 and followed-up till treatment outcome and 2 ½ years thereafter.

Treatment success (cured and treatment completed) of the study group was 67.9% as 24.7% patients defaulted from treatment. Treatment failures and deaths during treatment were 5.2% and 2.2% respectively. The success rate among those initially susceptible to all drugs was 66.8%. While it was 66.6% in patients initially resistant to more than one drug. However among 6 patients who had initial resistance to INH and rifampicin with or without resistance to other drugs, only 1 was cured. The development of drug resistance during treatment was seen in 1.3%. The proportion of bacteriological positivity and mortality during follow up was significantly higher among patients who defaulted from treatment. Relapses during the intervening period were 11.4%.

Fully intermittent CAT I regimen was effective in programme conditions, irrespective of the pre-treatment drug susceptibility status. A high proportion of defaults vitiated the treatment success of the cohort. The study findings underscore the importance of strict adherence to the programme guidelines for successful treatment completion and a lasting cure.

Key Words: *Treatment Outcome; DOT; Metropolitan City; Cohort Study.*

048: JOURNEY OF TUBERCULOSIS CONTROL MOVEMENT IN INDIA: NATIONAL TUBERCULOSIS PROGRAMME TO REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

P Kumar: Ind J TB 2005, 52, 63-71

This article is based on the presentation delivered during the 59th National Conference on TB and Chest diseases organized by TAI held at New Delhi. The presentation passes through the saga of important landmarks of the past dealing with era of pre-chemotherapy, conventional and SCC over two decades and the present era of DOTS spanning more than a decade. It also touches upon the likely challenges to be faced in the near future for TB control

In the era of pre-chemotherapy, TB has been recognized as one of the most ancient diseases as it has been documented in the Vedas and Ayurvedic Samhitas as early as 2000 BC. In 1882 discovery of TB bacilli by Robert Koch inspired many facets of research in prevention, control and therapeutic aspects of the disease. The only available mode of treatment during pre- chemotherapy era was isolation, providing good food and ventilation in a sanatorium. In India, the first open-air sanatorium was established in Ajmer during the year 1906. The Tuberculosis Association of India was established in 1939. In 1948, Dr. J. Frimodt Mollar introduced BCG vaccination in India and around the same time, BCG laboratory was established at Guindy, Chennai.

The development of anti-TB drugs commenced since the 1940s and it provided a global impetus to the efforts to control TB. In 1946, the Bhore Committee recommended the establishment of an organized domiciliary service for treating TB. A TB division was set up under the Directorate General of Health Services, New Delhi in the late 1940s. Dr. P. V. Benjamin was instrumental in initiating the National Sample Survey, which revealed for the first time the enormity of problem of TB in India. NTI, Bangalore was established in 1959 with the primary objective of formulating a nationally applicable programme for TB control. After pilot testing NTP in Ananthpur district in 1961, the programme was implemented in a phased manner to cover 364 districts of the country in 1962. During the era of conventional chemotherapy (1961-86), the treatment for TB lasted for 12-18 months and hence compliance to treatment was a problem.

The Chingleput study on efficacy of BCG vaccination initiated by Dr. Raj Narain in 1968 revealed that it did not offer protection against pulmonary TB. However, it was decided to continue the policy of BCG vaccination in children as it gives protection against childhood forms of TB.

The introduction of Rifampicin and Pyrazinamide in treatment regimens has been very important milestones in the fight against TB during the era of SCC (1986-1993) as the duration of treatment was reduced to 6-8 months. The SCC was result of the British Medical Research Council trials conducted in East Africa, India, Hong Kong and Singapore which was pioneered by Dr. Wallace Fox.

In 1992, an in-depth review of the NTP undertaken by GOI and WHO which revealed several glaring deficiencies in implementation of the programme. The GOI stepped up TB control efforts by implementing the RNTCP which adopted the DOTS strategy, in a phased manner since 1993. The expansion of the DOTs strategy in India is one of the fastest in the world and is continuing in planned manner to cover the entire country by the year 2005. The programme has shown the achievements of high

sputum conversion and cure rates among the TB patients and had also averted a large number of TB deaths. DOTS strategy has been one of the most cost effective health interventions. However, DOTS should be implemented correctly and sustained over a period of time in order to be successful. Operational research to monitor the over all performance of RNTCP in the long run has also been undertaken. Due importance are given to quality assurance network in sputum microscopy under RNTCP, quality assurance of drugs and re-vitalization of State TB Training and Demonstration Centres (STDC). Modalities have been worked out to involve medical colleges, private practitioners and NGOs in the RNTCP to increase case detection.

The future thrust areas in the TB control would be in the fields of External Quality Assurance (EQA) of microscopy centres, Human Resource Development (HRD), Drug Resistant Surveillance (DRS), initiatives in IEC and management of MDR TB cases under DOTS plus.

Key words: *Chemotherapy, RNTCP*

Total: 14

BCG AND TUBERCULIN TEST

BCG AND TUBERCULIN TEST

049: FINDINGS OF BCG SCAR SURVEY IN BANGALORE CITY

VK Chadha, MS Krishnamurthy, AN Shashidhara and V Magesh: *Indian J Prev Soc Med* 1997, 28, 81-89.

TB is widely prevalent in India. As disease surveys are too expensive and difficult, the assessment of TB situation in developing countries is preferably done by subjecting a representative sample of children without BCG scar to tuberculin testing. Prior to a tuberculin survey in school children of Bangalore city, a cluster sample, household survey was undertaken during September-November 1995 with the objectives of ascertaining the proportion of children aged 5-7 years with BCG scar and also to find the proportion among them attending schools. It was also decided to include 12-23 months old children to ascertain the recent BCG vaccination coverage in the city among the targeted population under UIP.

From 2100 identified localities of Bangalore city, each of which was considered as a cluster, 60 clusters were selected for the study by simple random sampling. One fifth of the selected clusters were from slums. From the selected households in each cluster, inquiries were made about the presence of children of the required age groups of 12-13 months and 5-7 years. From every cluster, 7 children each from both the age groups were registered and their BCG scar status recorded. Information on BCG vaccination status of children was obtained from immunization cards. In case of their non-availability, the information was collected by oral questioning.

The results of the survey showed BCG scar was identified in 71% and 74% of the children aged 12-23 months and 5-7 years respectively. The scar could not be identified in 20% of the children vaccinated according to the information culled from immunization cards. The results revealed that 38% of the children aged 12-23 months received BCG vaccination at private health agencies, 60% at Government Health Institutions and the remaining 2% were vaccinated by out reach services. The scar identification was higher among those vaccinated by private health agencies compared to those vaccinated at government institutions. Almost all children (99%) aged 5-7 years were attending schools.

It appeared that BCG vaccination coverage was higher than the observed BCG scar rates. Private health

agencies played an important role in the immunization programme. A lower scar identification in children vaccinated at Government Health Institutions suggests a need to examine the vaccination technique and cold chain management observed in these institutions. The high proportion of children attending schools is an encouraging factor for carrying out studies targeted at 5-7 years age group in schools.

Key Words: *Cluster, Survey; BCG scar; Immunization Card; BCG Vaccination;*

050: BCG-DO WE HAVE TO CONTINUE TO USE, YES ?

P Jagota: *NTI Bulletin* 1998, 34, 70-71.

The TB prevention trial and efficacy of BCG vaccines used in Chingleput is a world famous study. The write up on the first report of this study in 'Indian Express' proclaimed "TB vaccine is worthless says ICMR". Following this, the Government of India changed its policy. When the second report came 'Indian Express' again hit the headlines saying "TB vaccine is worthless says ICMR". Why this controversy? This controversy is basically due to ignorance about BCG, etiopathogenesis of TB, genesis of the trial and mis-interpretation of the latest report on findings of Chingleput BCG trial.

The childhood forms of TB occur by dissemination through blood vessels and lymphatics. In adults, few virulent TB bacilli in healed lesions can flare up any time in the future, breakdown into pulmonary disease leading to adult type of pulmonary TB. BCG is given for: 1) Prevention of primary disease; 2) Reduction of haematogenous dissemination and 3) Prevention of flaring up of old healed TB lesions of primary complexes in the lungs. Only the adult type of Pulmonary TB is responsible for maintaining the transmission of infection in the community. The mass BCG campaign in 1951 was started all over the country with the objective of controlling TB in the community, but the BCG trials conducted globally showed varying protection rates ranging from 0-80%. The Chingleput trial was a result, of the concern of planners, policy makers and TB workers. The findings showed no protection against adult forms of TB. The prevention of dissemination and producing childhood forms of TB was not studied in this trial.

ICMR in its Bulletin clearly states BCG vaccine interferes with the haematogenous spread of tubercle bacilli which could otherwise result in fatal forms of TB like TB meningitis and miliary TB. Therefore, GOI revised its policy of giving BCG to all children within 1st year of age through UIP. The GOI's decision to continue vaccination of children has prevented millions of children from dying of serious forms of TB or from becoming mentally and physically handicapped. The reduction in above forms of TB have been noticed by the present day practicing physicians. Ironically, the recently published second report of the trial showed that BCG confers more benefits to children and it provides some protection against adult forms of TB, which is due to endogenous reactivation.

Key Words: *BCG; Chingleput Study; BCG Policy.*

051: A COMPARATIVE STUDY OF TUBERCULIN REACTION TO 1 TU AND 2 TU OF PPD RT 23

VK Chadha, PS Jagannatha, AV Nagaraj, D Narayana Prasad and N Anantha; Indian J TB 2000, 47, 15-20.

Most tuberculin surveys in India have used 1TU PPD RT23 with Tween 80 as per WHO guidelines. The NTI, Bangalore, has proposed a nation wide study to estimate the ARTI in different parts of the country. Some experts including the IUALTD have suggested use of 2TU of PPD RT23 with Tween 80 for the proposed survey since they believe reactions with 1TU dose are softer and inexperienced readers are prone to commit errors in reading the soft reactions. Hence it was thought a comparative study of the use of the 2 doses of tuberculin would be appropriate. The objectives of the study were (i) to compare the tuberculin reaction sizes of 1TU and 2TU doses of PPD RT23 with Tween 80 (ii) to decide which of the two doses has a better correlation between reading of the standard reader and (iii) newly trained readers and to compare the rates of unpleasant skin reactions to either dose.

The study was conducted in 5-9 year old school children in the year 1998 in Anekal taluk of Bangalore district. The study was conducted using a double blind design wherein each child was subjected to dual testing with the two doses of PPD RT23 with tween 80. The tuberculin vials and child cards all were pre-coded for the dose to be given on a particular arm. Therefore, the sites of injection for the two tests were randomized. The same tester performed all the tests in the study. As per standard

procedure the reactions were read on the 3 day by palpating the induration and measuring its maximum transverse diameter by a standard reader and two trained readers- Reader I and Reader II separately and were also recorded independently. The presence or absence of unpleasant skin reactions at the test site like oedema, bullae, vesicles and necrosis were recorded at the same time. Children among whom injection of either of the 2 doses was unsatisfactory and children whose reactions could not be read by all the 3 readers were excluded from analysis. Data analysis was done using SPSS and Epi-Info software packages.

In all 609 children without BCG scar were registered for the study. The data of 537 children was analysed after excluding those with unsatisfactory tests and those whose reactions could not be read by all the three modes.

The frequency distribution of tuberculin reaction sizes to 1 TU among children without BCG scar showed a bimodal distribution and a clear demarcation for identification of the children probably infected with *M. tuberculosis* was observed at 17 mm. However such a demarcation could not be observed with 2 TU dose. The distributions of reactions to 1TU as read by Readers I and II were statistically similar to that of the standard reader. The frequency distributions of reaction size to 2 TU as read by the 3 readers were also similar. There was high degree of correlation between Standard Reader, Reader I and Reader II for reaction sizes for both 1 TU and 2 TU. Reactions ≥ 17 mm were termed as large reactions while those 10-16mm in size were termed as moderate reactions. A significant proportion of children with moderate reaction to 1 TU showed large reaction to 2 TU. Almost all the children with unpleasant skin reaction to the 2 TU dose had similar reactions to 1 TU as well.

The results obtained in this study do not support the hypothesis favoring a shift over to the use of 2 TU dose of PPD RT23 with Tween 80 for TB surveys in India.

Key Words: *Surveys; PPD RT23 with Tween80; Epidemiology.*

052: TUBERCULIN TEST

VK Chadha; Indian J Pediatrics 2001, 68, 53-58.

At last an article that puts to rest all ambiguity and speculation shrouding the interpretation of tuberculin test results. The author cautions that the tuberculin test only

detects the presence or absence of tuberculous infection and that the test should not be the sole investigation for diagnosing TB even in children.

The tuberculin, 1 TU of PPD RT23 with Tween 80 is recommended for use in India as it is more specific in our situation. This was originally prepared by SSI, Copenhagen and freeze-dried form supplied to BCG Laboratory, Guindy which reconstitutes and supplies the tuberculin to other parts of India. Other tuberculin preparations available in the market may not be standardized. Intradermal injection of 0.1 mm of 1TU PPD RT23 is administered conventionally on the volar aspect of left forearm using a standard tuberculin syringe and the induration at the test site read 48-96 hours later. A satisfactory test should raise a flat pale pea size weal with clear pits of hair follicles and there should be no leakage of tuberculin.

The tuberculin test is based on the principle that individuals harboring tuberculous infection develop delayed type hypersensitivity reaction at the test site. The window period for the sensitization to occur following infection takes 4-8 weeks. Not all tuberculin reactions are attributed to infection with tubercle bacilli. The reaction may also be attributable to non-specific sensitivity due to infection with environmental mycobacteria or BCG induced tuberculin sensitivity. The essence of interpretation of the test is that larger the size of the induration, higher is the probability of it being due to infection with tubercle bacilli. Also other circumstances including the purpose for which the test is administered is to be taken into account while interpreting the test results. Reaction sizes of 15 mm and above indicate infection with tubercle bacilli while those less than 5 mm suggest absence of any type of mycobacterial infection except in those with severe degree of immune suppression. Reactions with indurations between 10-14 mm could be due to cross sensitivity induced by environmental mycobacteria, BCG induced tuberculin sensitivity or infection with tubercle bacilli. It is more likely to be due to infection with tubercle bacilli in case the child has had contact with a smear positive case of pulmonary TB. Induration between 5-9 mm are often due to non-specific sensitivity or BCG induced tuberculin sensitivity. However, in an immuno compromised child it could be attributable to infection with tubercle bacilli. When the test is used for screening apparently healthy children for TB, before subjecting them to further investigations, a lower cut-off level may be considered to denote infection, while a higher cut-off level may be used

when the test is performed for deciding on the provision of chemoprophylaxis.

The article concludes making a reference to the interpretation of a repeat tuberculin test, the invalidity of BCG test and also about newer tuberculins.

Key Words: *Tuberculin Test; Induration Size; Infection; Tubercle Bacilli; Non Specific Sensitivity; BCG induced Sensitivity.*

053: PROTECTIVE EFFECT OF BCG AMONG CHILDREN VACCINATED UNDER UNIVERSAL IMMUNIZATION PROGRAMME

VK Chadha, L Suryanarayana, N Srikantharamu and P Kumar: Indian J Pediatrics 2004, 71, 1069-1074.

A case control study was undertaken by NTI, Bangalore to assess the protection offered by BCG vaccination against TB rendered under the UIP, as there was no scientific data pertaining to the Indian context available in the country.

This study was conducted among children aged 1-14 years with suspicion of TB, attending pediatrics department of 2 hospitals in Bangalore, namely St. Martha's Hospital and Vani Vilas Children Hospital, Bangalore. Only the children residing within 30 kms radius from the city were registered into the study and subjected to detailed clinical examination and investigations. The presence of BCG scar was taken as evidence of vaccination. Modified Steagen Jones scoring method was adopted for diagnosing TB. Children with score of ≥ 7 were considered as TB cases. Children residing in the neighbourhood of cases were similarly investigated and those scoring ≥ 4 were labeled as controls.

A total of 118 age-sex matched case-control pairs were identified and the final analysis was confined to 113 cases and 109 controls after excluding children with doubtful BCG scar. A low protective effect of BCG vaccination at 31% (not significant, statistically) was observed against TB - all forms combined, among children vaccinated under the UIP. The protective efficacy against extra-pulmonary TB was observed to be higher than for pulmonary TB but it was not statistically significant. Inadequate matching with respect to socio-economic status and deficiencies in vaccine administration could be some of the limitations of the study. The protective effect of BCG vaccine against TB meningitis and miliary TB could not be specifically evaluated in this study owing to small

numbers. The authors conclude by stating that it would be appropriate to conduct further studies on protection rendered by BCG vaccination against TB meningitis and other severe forms of TB. Nevertheless, till such time the current BCG vaccination policy needs to be adhered to.

Key Words: *BCG; Protective Effect.*

054: TUBERCULIN SENSITIVITY AMONG CHILDREN VACCINATED WITH BCG UNDER UNIVERSAL IMMUNIZATION PROGRAMME

VK Chadha, PS Jagannatha and P Kumar: Indian J Pediatrics 2004, 71, 1063-1068.

The information on the tuberculin sensitivity in BCG vaccinated children under the UIP in India, was fairly limited. So, the large volume of data available from the nation-wide tuberculin survey was analyzed to compare tuberculin sensitivity patterns in children with and without BCG scar and also to study their trends with age.

The database comprised of 45,988 children 1-9 years of age with BCG scar and 54,227 children without BCG scar residing in selected rural areas of northern, eastern and western zones of India. The children were subjected to tuberculin testing using 1 TU PPD RT 23 with Tween 80 procured from BCG laboratory, Guindy. Trained personnel performed the tuberculin test using

Mantoux technique. The maximum transverse diameter of induration was measured after about 72 hours. The readers were blinded to the BCG scar status at the time of reading the reactions. About 45-60% of the BCG vaccinated children elicited reactions <5 mm in size and about 70-80% had reactions <10 mm. Therefore, in the majority of children (showing tuberculin reaction of <10 mm), BCG-induced tuberculin sensitivity does not interfere with the interpretation of the tuberculin test. The study also revealed that a proportion of reactions among BCG vaccinated children in 5-9 mm, 10-14 mm and 15-19 mm range may be attributable to BCG vaccination. Therefore, reactions between 10-14 mm and especially 15-19 mm among the vaccinated children are to be interpreted carefully. However, 19 mm was observed as the upper limit for BCG induced tuberculin sensitivity and all reactions ≥ 20 mm in size may be considered to be due to infection with tubercle bacilli, irrespective of the BCG vaccination status.

Considering that BCG induced tuberculin sensitivity depends on various factors like dose and type of vaccine, age and technique of vaccination, time gap between vaccination and tuberculin testing and also on racial factors, the findings of this study may not particularly be applicable to settings in other countries.

Key words: *Infection; Tuberculin Test; BCG Vaccination.*

Total: 6

BACTERIOLOGY

BACTERIOLOGY

055: SERODIAGNOSIS OF PULMONARY TUBERCULOSIS AND EVALUATION OF TWO ELISA KITS

Sujatha Chandrasekaran, MM Chauhan and N Parimala:
Indian J TB 1996,43, 159-162.

Sputum microscopy plays an important role in the diagnosis of pulmonary TB. However, rapid and specific diagnostic tests are not available for the diagnosis of smear negative cases and extrapulmonary TB. ELISA helps in rapid serological diagnosis of many conditions. ELISA kits using different antigens are being used for diagnosis of TB. The objective of this study was to evaluate two TB ELISA kits Andelisa Ig G (A60) and Kreatech Ig A (KP90), in terms of their sensitivity, specificity, accuracy and predictive value in respect of their positive diagnosis.

The cases for the study were newly diagnosed TB patients attending the LWSTC, SDS. Sanatorium and patients of non-tuberculous chest disease from M.S.Ramaiah Medical College Hospital, Bangalore. The controls were normal healthy blood donors from Jayadeva Institute of Cardiology, Bangalore. Serum specimens were obtained from the cases and controls and subjected to ELISA tests. Sputum specimens were collected from the cases and subjected to AFB microscopy and culture for *M.tuberculosis* using modified Petroff's method. The study population was divided into four groups: Group 1-Controls; Group 2-Patients with non tubercular lung disease; Group 3- Newly diagnosed pulmonary TB patients; all smear negative and culture positive cases (S-C+) and Group 4- Newly diagnosed smear positive and culture positive cases of pulmonary TB (S+C+). All the specimens were subjected to ELISA test using standard protocol. Taking culture results as the gold standard, sensitivity, specificity, accuracy and predictive value of positivity were calculated. The mean titer of the controls and cases were compared and significance was tested using 't' test.

A total of 317 cases were studied. The cut off point (mean + 1SD) was taken from controls. With this cut off point, it was seen that 16.2 % of the normals, 47.6% of the non-tuberculous patients, 53.9% of the smear negative culture positives and 48.2% of the smear and culture positives were declared positives using the KP90 test. A lower rate was seen among controls with the A60 ELISA indicating a higher specificity. Taking culture as the standard, the specificity was 84% using KP90 and

92% using A60. The sensitivity, accuracy and positive predictive values were 49.7%, 61.5% and 56.1% with KP90 and 48.3%, 71.3% and 75% respectively with A60. Infection with *M. tuberculosis* induces an antibody response, which can be detected and measured. But the antibody activity does not correlate with the severity of the disease. In this study low level of antibodies were found in many smear positive cases. Overlap of antibody levels were seen between cases and controls. Hence these serodiagnostic tests are of limited value in the diagnosis of pulmonary TB. In case of smear negative patients, till an extensive evaluation of the antibody tests are made, these tests should be interpreted with utmost caution.

Key Words: *ELISA kits; Evaluation; Cases; Controls; Serodiagnosis.*

056: DRUG SENSITIVITY AND VIRULENCE OF *M. tuberculosis* GROWN IN THE PRESENCE OF CARBON DI-OXIDE

MM Chauhan and VK Challu: **Indian J TB 1996,43, 155-158.**

Despite the discovery of *M.tuberculosis* over a century ago, there is a dearth of information on its fundamental physiological capabilities, genetics, drug resistance and specific virulence determinates especially mechanisms of pathogenicity under increased CO₂ tension. Although CO₂ is not essential for initiating primary growth, it stimulates greater and faster growth. The objective of this study was to find out the growth and virulence of sensitive and resistant *M.tuberculosis* in the presence of 10% CO₂.

The study was carried out using 1005 specimens received at the NTI, Bangalore from February to May 1990. After subjecting all specimens to smear examination by ZN method and culture by modified Petroff's method, the sediments were inoculated on 4 Lowenstein Jensen (LJ) slopes. Randomly two of these slopes were incubated in the presence of CO₂ (Method A) and two in the absence of CO₂ (Method B). The positive cultures were subjected to routine identification and sensitivity tests. Coded isolates were inoculated into guinea pigs and the animals were sacrificed after 6 weeks to assess the extent of gross disease in different organs. The categorization of low or high virulence isolates was as per the previous published reports.

Of the 1005 specimens, 219 were culture positive. Of the 219 isolates 98 (44.7%) were found sensitive to all drugs and the remaining 121 (55.3%) resistant to one or more drugs. Method A was superior to method B for the growth of strains sensitive to all drugs. However, the yield of drug resistant mycobacteria was similar by both the methods.

Subjected to virulence study, method A was superior to method B and the percentages of low and high virulence were 73.8 and 26.2 for method A compared to 45.7 and 54.3 for method B respectively. Thus, the presence of 10% CO₂ enhances the growth of sensitive bacilli and facilitates the detection of low virulence isolates sensitive to INH.

Key words: *Carbon Dioxide; M. tuberculosis; Growth; Virulence.*

059: RELIABILITY AND APPLICABILITY OF SEROLOGICAL TESTS IN THE DIAGNOSIS OF TUBERCULOSIS.

MM Chauhan: NTI News letter 1997, 33, 56-61.

Majority of TB patients suffer from pulmonary lesions and the recommended tools of diagnosis for pulmonary TB are smear microscopy and chest radiography. Difficulties are faced when diagnosing smear negative pulmonary TB and extra pulmonary TB. Culture as a diagnostic test, which is not easily available in India, is time consuming and technically demanding.

Most sero-diagnostic tests based on antibody detection are not found reliable in Indian population. The reliability of these tests have been calculated taking into account their sensitivity, specificity and predictive value of positivity. Sero-diagnosis should not be resorted to diagnose new smear positive pulmonary TB patients as well as in assessing the prognosis of treated cases of pulmonary TB. Sero-diagnosis may have some applicability for diagnosis of extra-pulmonary TB patients, but at present no ideal sero-diagnostic test has been developed for these patients.

Key Words: *Serodiagnosis; ELISA; Sensitivity; Specificity; Predictive Value.*

058: ASSESSMENT OF TRISODIUM PHOSPHATE FOR STORAGE AND ISOLATION OF MYCOBACTERIA IN A SINGLE STEP CULTURE METHOD

MM Chauhan, B Mahadev, VH Balasangameshwara and N Srikantharamu: Indian J TB 1999, 46, 29-36.

Literature on transport media, for transport of sputum specimens from a rural set up to the laboratory for isolation of mycobacteria are very sketchy. With the implementation of the RNTCP and undertaking of drug resistance surveillance in the country, the need for an appropriate transport media is being felt acutely. An ideal transport medium should have more of decontaminating property and at the same time it should be less lethal to mycobacteria. The method should be easy to perform, have suitable chemicals which are also easily available. Cetyl Pyridinium Chloride (CPC) which is used as a transport media, is costly, not easily available and needs sophisticated laboratory equipment. Trisodium Phosphate (TSP) with Benzalkonium Chloride is another transport medium that has been used. However it has the short coming of not being operationally convenient. Hence Vasanthakumari et al, improved the method by avoiding the use of Benzalkonium Chloride and made it operationally convenient. The present study was undertaken to reassess the merits of TSP, for storage of specimens and isolation of mycobacteria. The Modified Petroff's method (MP) has been used as the control for this assessment because it is an accepted standard method. The objectives of this study were; 1) To assess the relative merit of TSP as storage medium in terms of overall culture positivity and contamination rate compared to the MP method among both smear positive and smear negative specimens and (2) To study the effect of storage on culture positivity and contamination.

Three hundred (300) smear positive and 299 smear negative sputum specimens were allocated randomly to TSP/MP methods, stored up to 8 days and then processed, in order to assess the merits of TSP as a medium of transportation and isolation of mycobacteria.

The overall culture positivity was 51% and contamination rate was 0.7% by the TSP method compared to 39.8% and 10.2 % respectively by MP method. The proportion of positive cultures among smear positive specimens was 90% in the TSP method while it was 77% in the MP method. The contamination rate of 0.6% was significantly less in TSP method compared to 11.5% in

MP method. Culture results of smear negative specimens indicated significantly more contamination in MP method (9.1%) compared to TSP method (0.7%). Thus the yield of cases was more and contamination rates less by TSP compared to MP method.

Another important finding of the study was that sputum positive specimens could be stored up to 8 days in the TSP solution, with significantly less killing of mycobacteria and a lower contamination rate. However, in respect of smear negative specimens, the TSP method compared to the MP method yielded fewer positive cultures when specimens were stored for more than 4 days.

Key Words: *Single Step Culture; Culture; Sputum Storage; Transport Medium; Trisodium Phosphate.*

059 : COMPARISON BETWEEN RAPID COLORIMETRIC MYCOBACTERIAL ISOLATION AND SUSCEPTIBILITY TESTING METHOD AND CONVENTIONAL METHOD USING LJ MEDIUM

B Mahadev, N Srikantharamu, P James, PG Mathew and R Bhagirathi: Indian J TB. 2001, 48, 129-134.

The TB epidemic has started receiving global attention since the last decade and the HIV epidemic has significantly contributed towards this scenario. The rising levels of drug resistance in TB has become a potential threat to TB Control programme. Drug susceptibility testing is being carried out by the proportion method. This procedure has remained the gold standard for a long time. However this procedure takes almost 21 days to grow mycobacteria which is too long and does not meet the world wide demand for quick laboratory diagnosis, rapid susceptibility and identification tests.

The BACTEC (460 MTB) system was the first broth based system which could provide rapid result and has been in use for many years. This system has certain demerits and also requires constant monitoring and is labour intensive. These drawbacks have been overcome to some extent in the MB/BacT-240 system, which is a fully automated colorimetric detection system. The working principle of MB/BacT-240 system is based on mycobacterial growth detection by a colorimetric sensor. If the microorganisms are present, carbon-di-oxide is produced as the organism metabolizes substrate glycerol. The colour of the gas permeable sensor at the bottom of each culture bottle changes from dark green to light green or yellow resulting in increase of reflectance in the unit,

which is monitored every 10 minutes by the system using infra red rays. As and when the result flags positive, there is a beep from the corresponding cell in the unit. At the time of beep approximately 10^6 to 10^7 organisms per ml are present in the bottle.

The objective of the study was to evaluate mycobacterial isolation rate, Mean Detection Time (MDT) and reliability of susceptibility as well as identification procedures with regard to clinical specimens by colorimetric and conventional methods. A total of 205 clinical specimens were processed by modified Petroff's method and then inoculated into MB/BacT-240 system bottles and on LJ medium slopes. A total of 101 isolates were detected by both the methods: the recovery rate was 57.1% (117/205) by the colorimetric method and 55.1% (113/205) by the conventional method. Contamination rates were 1% and 6.8% respectively. The MDT including susceptibility testing time was 28 and 52 days respectively. Highly significant difference was observed between the two sample means in the colorimetric and conventional methods.

Colorimetric method enables rapid detection and drug susceptibility testing, making it possible to get the results 4 weeks earlier compared to the conventional method. However, the Para-nitro Benzoic Acid (PNB) test by the colorimetric method needs standardization.

Key Words: *Mycobacterium Detection; Susceptibility Testing; Colorimetric Method; Conventional Method; Mean Detection Time.*

060: SURVILLANCE OF DRUG RESISTANCE TO ANTI-TUBERCULOSIS DRUGS IN DISTRICTS OF HOOGLI IN WEST BENGAL AND MAYURBHANJ IN ORISSA

B Mahadev, P Kumar, SP Agarwal, LS Chauhan and N Srikantharamu: Int J Tuberc 2005, 52, 5-10.

The CTD, Government of India, initiated a systematic Drug Resistance Surveillance (DRS), as per global guidelines, among new TB patients reporting to health facilities under RNTCP. The objective of the study was to measure the levels and pattern of resistance to anti-TB drugs among newly diagnosed sputum smear positive pulmonary TB cases in selected districts of India. The data obtained from the districts of Hoogli (West Bengal) and Mayurbhanj (Orissa) which was undertaken by NTI, Bangalore are presented in this article.

The study population comprised of 350 new smear positive patients diagnosed at 17 microscopy centres of Hoogli district between August 2000 to July 2001 and 343 new smear positive patients detected at 21 microscopy centres of Mayurbhanj district between August 2000 to May 2001. Two spot specimens were collected from all eligible patients and transported to NTI through a courier system after addition of Cetyl Pyridinium Chloride (1%) and Sodium Chloride (2%) At NTI, the centrifuged and washed deposit of transported specimens was inoculated on to the plain Lowenstein Jensen (LJ) medium for primary isolation. The positive cultures showing AFB were identified as *Mycobacterium tuberculosis* based on the results of growth on LJ medium containing Para-Nitro Benzoic acid and Niacin tests. All *Mycobacterium tuberculosis* cultures were subjected to drug susceptibility test by economic version of proportion method as per the IUATLD Manual for the National Laboratory Network. The critical proportion for declaring a strain as resistant to a drug was 1%. External quality assurance of Drug Sensitivity Testing (DST) of NTI laboratory was ensured.

Of the total 693 smear positive specimens subjected for culture from both the districts, 545 (78.6%) were culture positive for *M.tuberculosis*, 62 (8.9%) were culture negative and 86 (12.4%) were contaminated. Culture negativity and contamination rates were 7.9% and 9.9% from Mayurbhanj district and 10% and 14.9% respectively from Hoogli district. The resistance to any drug was 5.3% in Mayurbhanj and 16.7% in Hoogli district. MDR was 0.7% (95% CI: 0.0% - 1.7%) and 3.0% (95% CI: 1% - 5.1%) in Mayurbhanj and Hoogli districts respectively.

The study demonstrates that the levels of H, R and MDR in these two districts are within the expected levels, when compared to other studies conducted in India as per global DRS guidelines. However, in order to document success of RNTCP in reducing the levels of MDR TB, particularly in younger population, it is now necessary to conduct DRS in much larger population.

Key Words: *Drug Resistance, Surveillance.*

Total: 6

TUBERCULOSIS CONTROL

TUBERCULOSIS CONTROL

061: TECHNICAL BASIS OF REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

VK Chadha: NTI Bulletin 2002, 38, 3-10.

The DOTS strategy adopted by the RNTCP has shown promise especially in increasing cure rates of infectious TB cases. About half of the country has already been covered with RNTCP and the remaining half is expected to be covered in another five years. This article is intended to elucidate the technical basis of different operational aspects of RNTCP namely case finding and treatment strategies, the necessity of DOT, follow up procedures and the policy for chemoprophylaxis. The article has been written in the form of answers to questions frequently encountered during the course of various training programmes, workshops and other interactive sessions with TB workers. Efforts have been made to keep the article concise and easily comprehensible. The article elucidates the technical basis of RNTCP and is sure to benefit TB programme managers and physicians.

Key Words : DOTS; RNTCP; Treatment; Chemoprophylaxis

062: GLIMPSES OF TUBERCULOSIS PROGRAMME AND RESEARCH IN INDIA – YESTERDAY, TODAY AND TOMORROW

B Mahadev and P Kumar: Published in the book brought out by Ramakrishna mission, 2002, P 47-66.

This vivid description traverses through the saga of important milestones and landmarks of the TB Control Programme and Research in India. The article is slotted into three time frames, yesterday (1906-1992), today (1993 – 2005) and tomorrow (beyond 2005).

During the pre-chemotherapy era of yesteryears, the only available modality of treatment for TB was isolation, good food and ventilation in a sanatorium. The first sanatorium in India was established in the year 1906 at Tilaunia followed by the one at Almora in 1908 and the United Mission TB Sanatorium at Madanapalle in 1912. The forerunners for setting up the TB Association of India, in 1939, were Dr. Frimodt Moller and Dr. B K Sikand.

The era of conventional chemotherapy (1944-1981) witnessed the development of the anti -TB drugs which gave a global impetus for the treatment and control of TB. In India these drugs were initially tried out by Dr. Sikand, Dr. Sen, Dr. Pamra and Dr. Frimodt Moller. In 1948, the BCG vaccine was introduced in India by Dr. Frimodt Moller. The year also witnessed the establishment of BCG vaccine laboratory in Guindy. Dr. P V Banjamin, who played a stellar role in the mass BCG campaign in India is also credited for setting up of the premier TB Institutes of LRS, Delhi; NTI, Bangalore, and TRC, Chennai. In 1946, a TB division was set up under the DGHS, New Delhi. Following the path breaking findings of the NSS (1955-58) and studies by TRC it was decided to have a nationally applicable TB control programme in the country. Accordingly, NTI was established with the mandate to formulate a nationally applicable programme for TB control and to train key personnel for the execution of the programme. An integrated National TB Control Programme was pilot-tested in Ananthpur District of Andhra Pradesh in 1961 and the programme was expanded in a phased manner using R1-R5 regimens. Several important studies were conducted by NTI on different aspect of TB – epidemiological, operational, sociological and bacteriological – whose findings provided valuable inputs to the TB control strategies.

The era of SCC (1982-1992) brought about a reduction in the duration of treatment from 12-18 months to 6-8 months through the extensive clinical trials conducted by Dr. Wallace Fox and Dr. D A Mitchison. In 1983, the SCC utilizing regimens R_A and R_B were pilot-tested in 18 districts of the country and by 1986 was extended to cover 252 districts. The review of the TB programme by the GOI and WHO in 1992 highlighted the glaring deficiencies of the programme.

The era of DOTS (1993-2005) ensued with the formulation of the RNTCP which adopted the DOTS strategy. The pilot phase of the project was restricted to a limited population of 18 million between 1993-98. The hallmark of the DOTS strategy were political will and commitment, quality diagnosis using sputum microscopy, un-interrupted supply of quality anti-TB drugs, DOT, and

accountability in the form of systematic recording and reporting. A joint review of the programme was carried out by GOI and WHO and the committee recommended that the entire population of the country be covered by DOTS by 2005. DOTS is not a static strategy and should be implemented correctly and sustained over a period of time in order to achieve the desired results. The stride made in the expansion of RNTCP by the end of 2001 is exemplary of one of the fastest expansion of the strategy anywhere in the world. Emphasis has been laid on IEC activities and involvement of NGOs, Private Practitioners and Medical Colleges in the RNTCP. To monitor, evaluate and sustain the programme, areas of operation research studies were identified and executed.

The authors conclude that to quell the scourge of TB in the future, we have to act fast by enhancing the pace of decision making and translating it into action, re-focusing our attention on the important agenda of TB control through tight schedules of checks and counter checks, a change in our mindsets to achieve the desired milestones and accelerating the pace of implementation of DOTS.

Key Words: *Pre-chemotherapy Era; Conventional Chemotherapy; National Sample Survey; NTP; SCC; RNTCP.*

063: REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAM-A SUCCESS STORY

P Jagota: Indian J TB 2002,49, 69-75.

TB is one of the most ancient diseases, references to which are found in Vedas and Ayurvedic Samhitas. It continues to be one of the main causes of morbidity and mortality. In 1995, the global estimate for TB incidence was 8.8 million and there were 3 million deaths. India and its neighboring countries : China, Bangladesh, Pakistan and Indonesia account for more than half the incidence and India has nearly 30% of this global burden of disease. One person dies every minute of TB in India. There is little hope of reversing the trend unless serious attention is paid to perception of the disease and its therapy by patients and their relatives as well as priority is given at government and international levels.

Prior to the formulation of the NTP, a lot of research was conducted in the 1960's - the important ones being the NSS of 1955-58 and application of chemotherapy on

domicilliary basis in 1960. Sociological studies in 1963 and potential yield of pulmonary TB cases by sputum microscopy in 1967. Getting reliable information on magnitude and the extent of disease in the various cross-sections of population was not an easy task. The survey conducted by Frimodt Moller in 1952 in Madanapalle had indicated the problem of TB to be widespread in rural areas also, but this was not considered as being representative of the situation in the country. Hence, a special committee of ICMR was set up to address this issue and despite all odds, conducted the survey. The findings revealed that there were 4 Bacilliary cases per 1000 population and the disease was found equally prevalent in cities, towns and villages. Various studies on drug regimens were conducted by TRC, Chennai. Their studies also revealed that the virtues of sanatorium treatment such as bed rest, well balanced diet and good living conditions were unimportant provided adequate chemotherapy was prescribed. It was concluded that it would be appropriate to treat infectious patients in their own homes.

The finding of NSS and TRC researches revealed that the control of TB would require a totally new approach focusing on preventive aspects and finding and dealing effectively with infectious cases on a community wide basis. Hence, it was proposed to establish a national institute to formulate a TB Control Program and impart training to personnel who would implement the above programme. Thus the NTI was born in 1959.

The NTI always gave due recognition to the social aspects of TB. The social awareness study conducted by NTI indicated that TB was not a silent disease since 95% of bacteriologically positive cases were aware of symptoms and 52% sought care at the various general health services indicating that active case finding was not necessary. The study on potential of case finding demonstrated that technicians in the periphery could perform sputum microscopy effectively with training and regular supervision. This simple primary tool for diagnosis of TB could yield 45% of the total prevalent pulmonary cases in a district, during one year, through the DTP. These two studies were the main pillars in the formulation of the DTP. The district was selected as the basic unit of NTP.

The ultimate goal of NTP is to reduce the burden of TB gradually till it ceases to be a public health problem.

The objectives and the principles of the program are

1. Detection of maximum number of TB patients in the community.
2. Provision of effective treatment to all patients diagnosed.
3. To reduce their suffering and prevent disability and death.
4. To diagnose and treat patients near to their homes.
5. To integrate the TB services with the general health services for the self-reporting patients.
6. Free services.

DTP did not achieve the epidemiological impact on the magnitude of TB problem although, sociologically it saved a lot of human lives in terms of reducing the death rate from 225 per lakh to 47 per lakh. The review of the program by GOI, WHO and SIDA in 1992 lead to the formulation of RNTCP. This review highlighted the following shortcomings of NTP:

1. Inadequate allocation of funds, shortage of drugs, lack of political will.
2. Inability of general health services with which NTP was integrated to keep up with the population growth.
3. Over diagnosis by X-Ray and
4. Low treatment completion rates

The strengths of NTP were observed as: integration with the health services, felt-need oriented program, priority to sputum positive patients and free TB services.

In light of the above recommendations, RNTCP was designed and implemented in 1993. The fundamental principles of RNTCP include: 1. Political and administrative will; 2. Good quality diagnosis through sputum microscopy; 3. Good quality treatment with short course chemotherapy given under direct observation; 4. Adequate drug supply and; 5. Systematic monitoring and accountability for every patient.

Success of RNTCP is evaluated by: Expansion of RNTCP by the population coverage, Case detection rates, Ratio of smear positive to smear negative patients and Cure rates. Starting in October 1993, the RNTCP was implemented in a population of 2.35 million in 5 pilot

cities in different states. Currently over 425 million Indian population has been covered and the program is second only to that in China. Despite this rapid expansion, there has been no compromise on the quality of services and the results remain technically acceptable and in many areas are excellent.

The objective of the revised strategy was to achieve a cure rate of 85% among new smear positive patients through intermittent 3 days a week DOT. Treatment outcomes have been consistently good with 80% cure rates. Treatment success has increased for all types of patients between 1995 and the first two quarters of 1998. Cohort analysis of the patient put on treatment in the latest quarter has shown an average success rate of 83% and 3 months sputum conversion rate of 88%. It is heartening to know that quality of diagnosis remained excellent. Funding for RNTCP has been made available from our 5 year soft loan of US\$ 142 million from the World Bank. Each district with population of 2 million has a district TB control society which directly receives funds from the Central Government from the World Bank assistance.

The advisory council for the elimination of TB recommended in 1993 that, DOTS should be considered for all patients because of the difficulty in predicting as to which patient would adhere to a prescribed treatment regimen. Studies done by Murray et al 1991, Frieden et al 1995, Kumaresan et al 1998, Kenyon et al 1999, Zhang and Enarson 2000, Balasubramaniam et al 2000, Olle-Goig and Alvarez May 2001 have all shown that cure rates improved tremendously with DOTS. RNTCP can play a major role in treating patients of HIV with TB and DOTS is as effective in HIV infected TB patients as in those who are HIV negative.

WHO in 1996 reported that the emergence of drug resistance is indicative of an ineffective TB control program. Patients infected with MDR strains require longer duration of therapy and die of TB or continue to have TB despite optimal therapy. A large number of reports from different parts of the world have demonstrated that effective treatment programmes can prevent the development of drug resistance. Treatment of MDR-TB is difficult, expensive and often unsuccessful. Espinal et al in 2000 reported that DOTS prevents the emergence of MDR-TB and helps reverse its trend in the community.

In September 2001, TB experts from Medical Colleges all over India in a workshop held at NTI, Bangalore concluded that within 8 years of its implementation and 3 years of large scale service delivery, RNTCP has proved its credibility as the most effective and the only strategy to control TB in India. India is going in the right direction as far as the pace and quality of implementation of RNTCP is concerned.

Key Words: DTP; NTP; RNTCP; DOTS.

064: ROLE OF SENIOR TREATMENT SUPERVISOR IN REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

VN Saroja: NTI Bulletin 2002, 38, 8-10.

The RNTCP aims to reduce the transmission of TB as well as to reduce mortality and morbidity due to the disease. The performance of any programme depends upon the key persons involved. The STS plays various roles at different junctures in the programme. He is an important link between the health system and the patients, besides acting as a co-ordinator between the district and sub-district level of the health system and PHI. This article highlights the various roles of STS in the programme viz. as an educator, trainer, a captain of the treatment section, a supervisor, a planner, an organizer and so on.

Key Words: *RNTCP; Mortality; Morbidity; STS.*

Total: 4

X - RAY

X-RAY

065: FACTORS CONTROLLING THE QUALITY OF RADIOGRAPH AND QUALITY ASSURANCE

PS Ramamurthy: NTI Bulletin 1995, 31, 37-41.

The discovery of X-rays towards the end of the 19th century by Wilhelm Conrad Roentgen came as a big boon to the medical community, aiding diagnosis and treatment. The important characteristic of an X-ray is its penetrating power. This power depends on atomic number, thickness of the part of the body to be traversed, and the density of the material. The different tissues in the body produce different densities on the radiograph. This helps us to distinguish and differentiate the image of different tissues in the radiograph. This is called contrast. This X-ray image is taken on a photographic plate and then processed like a photographic film.

A good radiograph should have sufficient sharpness and radiographic contrast. Sharpness of image depends on geometric factors, motion and photographic factors. Contrast of the film is dependent upon film contrast, processing chemicals and radiation factors of objective contrast. Exposure factors in diagnostic radiography which are important are tube voltage, tube current and duration of exposure expressed in seconds.

Quality assurance programme for diagnostic X-ray units is aimed to ensure that the image produced is consistently of high quality giving maximum diagnostic information with minimum radiation exposure to the patient at minimal cost. By this repeat X-rays can be avoided thereby saving valuable film, reducing dose of radiation to patient and operator and also prolonging the life of the X-ray tube. Proper alignment and correct field size are necessary to give essential information for diagnosis.

Temperature of processing solutions, time of development, fixing and washing should be standardized taking into account manufacturers recommendations to get optimum results. Lastly but not the least, power line conditions also change the quality of the radiograph. It is better if the X-ray unit is connected to higher voltage so that current drawn is less for the same voltage. This will ensure maintenance of voltage and also ensure quality of the radiograph.

Key Words: *X-ray; Radiograph Quality; Quality Assurance.*

066: GENERAL INFORMATION ON MMR X-RAY UNITS AND ITS PRESENT STATUS

S Ravindra: NTI Bulletin 2002, 38, 4-7.

This article describes the various aspects of conventional and mass miniature radiography like the operating principles, advantages of MMR over conventional radiography, maintenance aspect etc. It also gives information about the services offered at NTI regarding training and maintenance of these MMR units.

The main objective of this article is to provide guidance on the technical and operational aspects of the MMR X-ray units to the district level programme managers. Some of the other aspects about the investment made by GOI for supply of MMR X-ray units to various districts under the NTP, the current status of MMR X-ray units in the country and the future action plan of NTI for keeping these units viable and in working condition are also covered.

Keywords: *X-ray; Diagnosis; Mass Miniature Radiography; NTP.*

Total: 2

MONITORING

MONITORING

067: PERFORMANCE OF NATIONAL TUBERCULOSIS PROGRAMME IN 1993: AN APPRAISAL

L Suryanarayana, K Vembu, R Rajalakshmi and C Satyanarayana: Indian J TB 1995, 42, 101-115.

This paper appraises the performance of NTP in terms of implementation, reporting, supervision, performance of case finding and treatment activities and availability of trained manpower and equipment, for the year 1993.

Four quarterly DTP reports on case finding and treatment activities and annual DTP reports on cohort analysis of the treatment results for the prescribed cohort periods emanating from the different DTP's constitute the material for this paper.

Analysis of the information in respect of implementation of DTP, at the national level showed that DTP's have been implemented in only 390 out of 480 districts. Many states were re-organizing their districts and splinter DTP's had been created without proper infrastructure. Out of the 390 implemented DTP's, only 252 (64.6 %) had been covered under SCC. Out of the expected 29,500 PHIs in the country, only 16,830 (56 %) had implemented the programme in the country. The various states showed a range from less than 50% to greater than 80% in respect of implementation of the programme. In respect of reporting, at the national level the efficiency was 78% by the DTP's and it was only 70% in respect of the PHIs. These shortfalls were basically due to inadequate supervision of the PHIs by DTCs. Only 41% of the PHIs had been supervised by the DTCs. Various deficiencies for this inadequate supervision have been identified. At National level DTCs have achieved case finding efficiency of 71% (of 400 s + ve cases) and at PHIs it is 36% (of 400 s +ve cases). There is a lot of variation in the performance of different states. At the national level smear positivity rate is only 12.3% for the DTC's and 4.8% for the PHIs as against the desired levels of 18% and 8% respectively. Strengthening of the laboratory services are required to improve the positivity rates. The smear confirmation among pulmonary cases is 20% at the DTCs and 24% at the PHIs as against the expected 35%. Rates below 35% indicate over reading of X-rays. The cohort period considered in this analysis was for the annual report of the year 1992. Only 34% of the patients under Standard / conventional

(SR) regimen made 12 or more monthly drug collections. In the SCC regimen, 44% of the patients in regimen A and 51.8% of the patients on regimen B collected ≥ 75 % of the doses expected. These levels of completion were not likely to have an epidemiological impact and not commensurate with inputs made. With regard to trained key personnel, only 43 (15%) of the reporting DTCs have full complement of trained team.

In conclusion, the remedial measures have to be taken to implement DTP in all the districts, improve reporting, ensure availability of full complement of trained key personnel, ensure effective and adequate supervision, improve case finding and improve case holding. To achieve all the above, provision of adequate organizational, administrative, financial and technical support are pre-requisite.

Key Words: *Performance; Indicators; Expectations; Achievements; NTP.*

068: PERFORMANCE OF THE NATIONAL TUBERCULOSIS PROGRAMME DURING 1996-A REPORT

L Suryanarayana, R Rajalakshmi, MV Jaigopal and SG Radhakrishna: Indian J TB 1999, 46, 11-20.

The NTI Bangalore has been monitoring the NTP since 1978. The DTP in 395 districts is being monitored through the quarterly and annual reports actually received. The percentage of DTP's being monitored accounts for 79% of the total districts in the country and 61% of the DTP's are covered under SCC. In all, 80% and 43% of PHIs have been implemented under the SR and SCC Regimens respectively.

Reporting efficiencies of DTPs and PHIs were 80% and 70% respectively during 1996. Only 33% of PHIs were supervised by the respective DTCs, at least once in a quarter during the year. Smear positivity of sputa examined was 12% and smear confirmation of pulmonary cases diagnosed by X-ray was 22% at DTCs. At PHIs, 90% of the patients eligible for sputum examination had been offered the test and smear positivity rate at PHIs was 5.8%.

National level composition of the TB cases diagnosed in a district was: smear positive (B) cases -

20%, X-ray (X) cases - 73% and extra-pulmonary (E) cases 7%. As regards treatment, out of only 182 SR annual reports received and analyzed, just 28% of the patients put on SR completed satisfactory level of treatment. And of the 120 SCC annual reports analyzed, 58% of the patients put on SCC completed satisfactory level of treatment. Since just 47% of the SR and 58% of the SCC patients completing treatment satisfactorily, had been subjected to final follow up sputum examination, the cure rates could not be calculated.

Only 277 DTPs reported on the availability of trained manpower and equipment. DTOs had been posted in 54.5%, SAs in 43%, TOs in 68%, X-ray Technician in 60% and LTs in 67% of the reporting DTPs. Full complement of trained manpower was available only in 10% of the DTPs. MMR with Odelca Camera was installed in 82% and supervisory vehicle was provided in 66% of the reporting DTPs.

While performance in fulfilling the NTP objectives in 1996 was considered to be short of expectations in all aspects, poor performance had remained more or less unchanged over the past 5 years.

Key Words: *Performance; Monitoring; Sputum Positivity Rate; Case Finding Efficiency; Treatment Efficiency.*

069: PERFORMANCE OF NATIONAL TUBERCULOSIS PROGRAMME JANUARY TO SEPTEMBER 1999 – A REPORT

SJ Savanur: Indian J TB 2001, 48, 25-30.

The performance of NTP is evaluated in terms of implementation, reporting, supervision and case finding and treatment activities during Jan to Sep 1999 in the NTP districts. The NTP is implemented in 440 districts. Of them 295 (67%) are providing SCC while the remaining are providing SR. Forty-one of the 295 SCC districts are now implementing RNTCP and these districts are monitored directly by Central TB Division, DGHS, Government of India.

The reporting efficiency for the 3 quarters was only 1003/1320 (76%), of which 27 had errors and had to be discarded. The reporting efficiency further came down to 65% when the PHIs reported to DTC. In only 8 states, all the districts had implemented DTP. The newly formed states were particularly lagging behind in implementing DTP.

Supervision of PHIs by core personnel of DTC at least once in a quarter is essential to ensure proper work standards including reporting and replenishment of supplies and equipment. Only 10% of the PHIs were supervised at least once in a quarter and only in 3 states this percentage rose to 20%. The reasons given for low performance were non-availability of the vehicle or diversion of the vehicle to other programmes, inadequate budget for POL, travel expenses and lack of motivation of concerned staff.

Coming to case finding, the National average for smear positivity rate of 12.5% at DTCs and 5% at PHIs is low. The main reasons for this are poor quality of specimens, inefficient sputum microscopy and lack of trained laboratory technicians. The ratio of smear positive to smear negative cases should be 1:1 as per WHO guidelines. At the National level, the ratio of new smear positive to new smear negative cases was 1:2.5. This ratio varied from 1:1.2 in Tripura to 1:6.7 in Assam.

During Jan-Sep 1999, a total of 7,91,022 cases were diagnosed, of whom 27% were sputum smear positive, 67% smear negative and 6% extra-pulmonary. Eleven states accounted for more than 90% of the total cases. A substantial number of the X-ray positive cases diagnosed were based on radiographs taken in private Institutions. In five states, the annualized case detection rate for new smear positive cases exceeded the expected 85 cases per lakh population, while it was only 13 cases per lakh population in 2 states.

The percentage of treatment completion at the National level was 30% for SR and 57% for SCC for smear positive patients.

Only 247 of the DTCs reported on the availability of Trained Core Personnel and only 13 of them have the full complement of core trained personnel. Non-availability of trained key personnel at DTCs may be due to lack of sanctioned posts, posts remaining vacant, lack of budget to depute key personnel for training and diversion of manpower to other schemes / programmes. The facilities of microscope and X-ray in the 247 reporting DTCs were 131 and 113 respectively. Only 78 had vehicle in working condition.

The performance of NTP is far below the expectation in all respects. Doctors at DTCs and PHIs still depend on X-ray diagnosis when it is well established that sputum microscopy is the preferred tool for diagnosis of

pulmonary TB. Non-availability of the trained manpower is the main cause for poor performance.

Key Words: *Performance; Reporting; Implementation; Case Finding; Supervision; Treatment Activities; NTP.*

070: MONITORING OF TUBERCULOSIS CONTROL PROGRAMME- RECORDING, REPORTING AND SUPERVISION

KP Unnikrishnan and PS Jagannatha: NTI Bulletin 2002, 38, 11-17.

The NTP has put in place a recording and reporting system to systematically evaluate the patient's progress and treatment outcome, as well as overall programme performance. The system includes a laboratory register that contain a log of all chest symptomatics and patients who had a smear test done; treatment cards that detail the intake of medication and results of follow up sputum examination; and the TB register which lists patients starting on treatment and monitors their individual and collective progress towards cure. A health worker is responsible for

supervising each administrative area or institution in the district and uses the district/sub-district TB register to monitor the progress and treatment outcome of all patients in that district. This provides the district or local health chief with rapid feedback on programme performance in the district. Recording and reporting system allows for targeted, individualized follow up to help patients who may not be making satisfactory progress and rapid assessment of the overall performance of each institution: district, state and at national level. There is a strong system of accountability and checks and balances that make false reporting of data difficult.

A good record/report demonstrates that services were provided to the patient and establish that services provided were necessary. Reporting is auditing of our own records. This helps the programme managers to evaluate the strengths and weaknesses of the system of TB case management.

Key Words: *NTP; Chest Symptomatics; Sputum Examination; Programme Managers; Case.*

Total : 4

INFORMATION, EDUCATION AND COMMUNICATION

INFORMATION, EDUCATION AND COMMUNICATION

071: A STUDY OF KNOWLEDGE, ATTITUDE AND PRACTICES OF PATIENTS CURRENTLY UNDER TREATMENT FOR TUBERCULOSIS AND DEFAULTERS, IN A BACKWARD AREA OF SOUTH INDIA:

Vijaya Raman, VK Chadha, AN Shashidhara, MV Jaigopal and Selvam: NTI Bulletin 1997, 33, 3-8

The overall efficiency of the NTP implemented through the general health services has been generally poor. The authors feel that several administrative, managerial and technical endeavours are necessary in identifying key factors that influence the efficiency of the TB control efforts from time to time. One such factor would be to assess the knowledge, attitude and practices of patients who are the end beneficiaries.

Therefore a study in Aundipatti taluk of Madurai district was conducted by Seva Nilayam Society, an NGO in collaboration with NTI, Bangalore to assess the knowledge, attitudes and practices of patients under treatment for TB in the study area with regard to chest symptoms, TB disease, its diagnosis and management and to study the reasons for default and treatment seeking behaviour of defaulters thereafter. A survey was conducted in a sample of 100 patients (66 males and 34 females) of ages more than 15 years who were undergoing treatment for TB from health care providers (PHCs, NGOs and qualified and unqualified private practitioners). Experienced SI interviewed the patients. Also 49 defaulters (patients, dropped out of treatment for more than 2 weeks) were interviewed with the help of a specially designed schedule to ascertain the reasons of default and on any further course of action taken by them.

The results of the study indicate that though the majority of patients were aware of most facets of the nature and curability of the disease, there were areas that required educative support and guidance. Also noteworthy was the fact that social stigma attached to the disease was not prevalent in the area. The health care providers were also partially responsible for the ignorance of the patients. Regarding the defaulters, 36% of them had resumed treatment from other sources for reasons ascribable to more faith in the quality of diagnosis and treatment, accessibility and convenient timings.

Key Words: *KAP; Survey; Chest Symptoms; Pulmonary Patients; Defaulters.*

072: IEC AND ITS ROLE IN THE CONTROL OF TUBERCULOSIS

PS Vaidyanathan and PK Dwivedi: NTI Bulletin 1998, 34, 62-63.

The acronym IEC stands for Information Education and Communication. It is an important tool for dissemination of health information. The objective of IEC is to inform, motivate and subsequently guide people into action to adopt healthy practices and life styles. Before imparting IEC, the educator should assess the knowledge and attitude of the people regarding the subject he wants to talk about and the strategy and the message should be planned accordingly. The media used for communication should also be chosen with care. Two-way communication is more likely to influence behaviour than one way communication. All barriers in communication - psychological, physiological, environmental and cultural should also be identified and removed.

Before any IEC activity is planned, it is important to identify the felt-needs of the people. Prior knowledge of customs, habits and beliefs of the people is important before preparing the strategy. Active learning in the form of group discussions, panel discussions and learning by doing should be encouraged. This principle is well illustrated by the Chinese proverb "If I hear, I forget; if I see, I remember; If I do, I know". The messages should be commensurate with the level of education, knowledge and understanding of the target group. Periodic repetition of key messages during communication reinforces learning.

IEC has an important role to play in the control of TB, as the disease is a major public health problem in India. Ignorance of symptoms, mis-beliefs and stigma attached to TB are important sociological problems, which perhaps deters people, especially women from seeking help. Non-adherence to treatment regimens is another important aspect. Many doctors are ignorant of standard anti-tubercular regimens. Proper IEC activities will help in combating these hurdles and hence this vital component for TB control should be strengthened.

The IEC messages directed towards patients and their relatives should emphasize that TB is easy to diagnose, treat and cure; that the treatment of TB is free in the government sector; people having cough lasting for more than three weeks should consult their doctors and so on.

To the health care providers the message should emphasize the reliability of sputum microscopy for diagnosis. To political leaders and funding agencies the scourge of TB should be highlighted and commitment for TB control should be sought. The choice of the appropriate media of communication should be done with care and may be through posters, films, wall paintings, tin plates, talks and so on. Sincere and dedicated efforts of all stake holders is paramount to ensure success of IEC in TB control.

Key Words: *IEC; TB control.*

073: A STUDY OF KNOWLEDGE, ATTITUDE AND PRACTICES OF MEDICAL PRACTITIONERS REGARDING TUBERCULOSIS AND ITS CONTROL IN A BACKWARD AREA OF SOUTH INDIA

A Vijaya Raman, VK Chadha, AN Shashidhara, MV Jaigopal and Selvam: NTI Bulletin 2000, 36, 3-7.

Tuberculosis continues to be major health problem in our country and is the single largest cause of loss in healthy life years in the productive age group. Though TB control programme has been in vogue for more than 30 years, it has not made a measurable impact on the disease situation. In spite of nearly half of bacillary cases of TB approaching general health institutions for relief of their symptoms, the case finding and case holding efficiency of these agencies is generally poor. More recently it has been reported that a majority of the chest symptomatics in cities first approach the private sector for relief and in rural areas one third of the diagnosed cases had approached the private providers. However, the diagnostic and curative abilities of these agencies were disparate and only a fraction of the diagnosed cases completed treatment which resulted in unsatisfactory cure rates. Such a scenario calls for periodic assessment of KAP of medical practitioners manning all types of treating agencies so that some of the factors adversely influencing diagnosis and treatment could

be identified and remedial actions taken up subsequently. Such studies are more relevant in remote and backward areas inhabited mostly by poor people with limited access to health care and where a large number of unqualified private practitioners provide service to the community.

With this background in view, a KAP study was carried out in Aundipatti taluk, a backward area in Madurai district of Tamil Nadu inhabited mostly by the poor and tribals who eke out a living without proper housing, sanitation and supply of safe drinking water. The survey was conducted among all the 96 Medical Practitioners in the area, after enlisting them by visiting and making enquiries with the PHCs, private practitioners, druggists and other knowledgeable sources like village leaders. Each medical practitioner was interviewed using a semi-structured proforma in an informal atmosphere. The KAP survey was conducted to assess the existing practices by all types of medical practitioners regarding diagnosis and treatment of pulmonary TB.

The results indicated that as elsewhere in India, even this region had a number of medical practitioners - there were 24 allopaths and 72 non-allopaths. The majority of the former and a significant proportion of the latter had adequate knowledge about the cause and symptoms of pulmonary TB and tools required for diagnosis and drug regimens. However, their practices did not necessarily follow their knowledge as evidenced in diagnosis, over-dependence on X-ray and disparities in treatment. This was more so among the non-allopaths. Most were aware of the consequences of irregular treatment.

There is vast scope for utilizing the existing network of medical practitioners to augment efforts to control TB. Hence information dissemination on scientific lines and guided involvement of medical practitioners is important.

Key Words : *KAP, Survey; Pulmonary TB; Defaulters.*

Total: 3

TUBERCULOSIS GENERAL

TUBERCULOSIS GENERAL

074: CHILDHOOD TUBERCULOSIS TODAY

P Jagota, HV Suryanarayana and VK Chadha: Journal of Internal medicine of India 1997, 8, 121-124.

TB is one of the main causes of mortality in the developing countries. Although most of the patients of TB are adults, it also affects children. Serious forms of TB like TBM and miliary TB contribute to deaths in significant numbers among the children. TB is transmitted to children from adult sputum positive pulmonary TB cases. Control of TB in children will depend upon the proportion of smear positive cases detected and properly treated. The problem of TB in children reflects that of TB in adults. Even though, the diagnosis of TB in children poses a great challenge, chemotherapy is capable of curing TB in all the diagnosed patients complying with prescribed period of treatment.

The disease can be classified into two types (1) Childhood form of TB which includes primary and miliary disease of lungs and all types of extra pulmonary TB such as pleural effusion, TBM, TB Spine, Renal TB, Tuberculous lymphadenitis etc., (2) Adult form of TB which occurs mostly in the lungs as a result of either reactivation of primary infection or re-infection.

The prevalence of infection among children has been observed to vary from place to place and prevalence rates of 5-10% on an average have been observed in various surveys carried out in different parts of the country. In all the surveys, infection rates were found to increase with age, being the lowest in the age group of 0-4 years. The precise estimates of the magnitude of TB disease in children are difficult to obtain. In most community based surveys the children below 5 years of age are not included and very little information is obtained from hospital based records. In rural areas of Bangalore, Prevalence rate of Pulmonary TB among children (5-14 years) was observed to be 0.3%, one-sixth of that in adults. The prevalence of bacillary disease was observed to be 0.1%. Almost similar rates of disease were obtained from urban slums of Bangalore and peri-urban areas of Bangalore in 0-14 years of age group. The morbidity among children depends upon the age of primary infection, history of contact, nutritional status etc. A higher incidence of the disease has been observed among infected children with tuberculin reactions of 20 mm or more. This risk is highest in the immediate period following infection.

Little is known about TB mortality rates in children. However, crude mortality rates have been reported to be higher in the infected group of children.

Diagnosis of childhood TB is based on the presence of generalized symptoms, symptoms related to the organ involved and a very high index of suspicion about the disease in an individual child. Cough is not a prominent symptom and haemoptysis and other chest symptoms are also very rare. There is no single specific test to diagnose childhood TB, hence, use of single or few tests often leads to over diagnosis. To minimize over diagnosis it is necessary to diagnose TB in children in an objective manner by taking detailed history, by applying a battery of tests like tuberculin tests, clinical, X-ray, bacteriological, histopathological examinations and finally applying the scoring system.

All children should be treated effectively with proper combinations and dosages of drugs. The prevailing regimens using the dosages per kg body weight are usually adequate for treating any kind of TB.

Routine chemoprophylaxis for TB has not been recommended in the program. But it can be offered on individual basis to the high-risk group of children. Thus, newborns and children below 6 years of age who are asymptomatic and exposed to smear positive pulmonary TB can be given chemoprophylaxis after excluding active disease in them. INH in the dose of 5mg per kg body weight is used for chemoprophylaxis. In case of children infected with HIV infection, it is recommended to give INH chemoprophylaxis for 12 months.

Various trials across the world have shown varying degrees of efficacy of protection with BCG vaccine from 0-80%. A significant rise in the incidence of TB among children has been observed after discontinuation of BCG vaccination programmes in some of the developed countries. Therefore, it appears that BCG gives protection against childhood form of TB. Presently, BCG vaccination is continued in India with some modification in its policy with age etc. BCG is given as a part of UIP.

The precise quantification of TB problem among children is more difficult. It is estimated to be much less compared to adults. However, with the introduction of the new risk factors like urbanization and demographic changes, the problem of TB is likely to be aggravated in

the coming years. It is much easier to prevent than to treat some serious forms of TB, which can lead to disability and death. By giving priority to smear positive cases in the programme, the childhood TB automatically gets priority.

Key Words: *Childhood Tuberculosis; Morbidity; Mortality; Diagnosis; Treatment; Chemoprophylaxis; BCG Vaccination; Control.*

075: PREGNANCY AND TUBERCULOSIS

P Jagota: Journal of Internal medicine of India 1997, 8, 119-120.

In spite of tremendous advances in chemotherapy of TB, pregnancy among TB patients is dreaded even today. Most physicians still advise women not to conceive during active disease and if conceived to get an abortion done. Physicians continue to give such advice due to lack of information. This article gives guidelines for dealing with such situations.

Available data indicates that incidence of TB could be higher in pregnant women than in the general population. TB seldom has any deleterious effect on pregnancy and generally the baby is healthy at birth. Premature births are related to the severity of the disease in the mother and due to her impoverished nutritional status. Congenital TB is a rare complication of maternal TB. The placenta usually serves as a strong barrier against tubercle bacilli. But in few cases severely damaged placenta can allow haematogenous spread along the umbilical vein. A newborn baby is at a greater risk of acquiring TB post partum especially if the mother is suffering from smear positive and untreated disease.

It was generally believed that the pregnancy aggravates pulmonary TB. Deterioration was said to take place in the early months due to hyperemesis and later in the puerperium. Studies in recent years have shown that uncomplicated pregnancy does not affect the course of pulmonary TB and pregnancy is not contra-indicated unless the TB lesions are very extensive. The prognosis in pregnant women with extensive active lesions is no worse than in a non-pregnant patient with the same type of lesions. However, all these conclusions are valid only when proper medical care is available for the treatment of TB and complications of pregnancy, if any.

Pregnant women with TB should be treated without delay, diagnosis being ideally based on sputum smear

examination. With the advent of highly bactericidal drugs like INH and Rifampicin, the pregnant women can be treated with 6-9 months SCC regimens. No teratogenic effects have been reported with INH and Rifampicin. Streptomycin and related group of drugs are contra-indicated. Till date, no congenital malformation has been reported with use of Pyrazinamide. Breast-feeding should not be discouraged in mothers receiving anti-TB drugs. Newborn babies should be treated appropriately as soon as diagnosis is made, the basic principles of treatment remaining same as for adults. However, Ethambutol should be avoided.

All anti-TB drug regimens can cause adverse reactions. These are usually minor but they can be occasionally serious and rarely life threatening. Clinicians should be aware of the reactions, which can occur and know how to manage them and weigh the benefit versus risk to the patient.

Compliance to therapy is the major problem in TB treatment. In developed countries non-adherence to treatment is to the tune of 20%, while in developing countries this is to the extent of 50%. Non-compliance can be improved by repeated motivation, timely defaulter retrieval actions and providing efficacious SCC regimens free of cost through the TB control Programme.

The patient may be advised to postpone pregnancy till the TB treatment is completed successfully. Therapeutic abortion is not advised for women developing TB during pregnancy. Pregnant women having chest symptoms or symptoms related to other organs should be investigated for presence of TB and managed efficiently by providing proper treatment.

Key Words: *Pregnancy; Tuberculosis; Management of Disease; Compliance.*

076: TUBERCULOSIS CONTROL AND ECONOMIC ISSUES

VK Chadha, PS Vaidyanathan and S Singh: NTI Bulletin 1999, 35, 3-7.

Tuberculosis is the world's leading killer among infectious diseases. It is responsible for 6.7% of all deaths and 18.5% of deaths of people in the age group of 15-59 years. The brunt of the disease burden is borne by those in the 15-59 year age group. No country can afford to lose its citizens in the prime productive years of their life. TB also kills more women than all other infectious diseases and all causes of maternal deaths combined. There

are few studies on the actual cost or consequences of TB on the family, community and the overall economy of our country. The economic consequences of TB are enormous. The magnitude of economic losses to the nation can be gauged from the fact that TB is the single largest cause of DALYs among adults in developing countries. In India TB accounts for 3.7% of total DALYs lost. (One DALY is equal to one lost year of healthy productive life).

Most communicable diseases are associated with poverty, undernourishment, overcrowding and unhygienic living conditions. Many studies have shown that TB is concentrated in those belonging to lower socio-economic groups, those living in *kutcha* houses and having lower literacy levels. The advent of the HIV epidemic has facilitated return of TB in wealthy countries and is expected to worsen the situation in poor countries. This upsurge in HIV related TB incidence would make the economic burden of TB much greater. Nearly 50% of TB cases report to Government health facilities for seeking relief but they are often not diagnosed. This leads to economic loss in terms of wages, production and expenses on general antibiotics, X-rays and so on. Anti-TB drugs, though provided free under NTP are in short supply, which leads to irregular and inadequate treatment and also encourages default. All these impose indirect costs to patients leading to debts and insecurity about their future. Incomplete and inadequate treatment increases the likelihood of MDR-TB. The cost of treating MDR-TB is beyond the scope of any health programme. SCC was introduced to overcome the problem of default. Though costlier, SCC leads to better patient

compliance and higher cure rates and cost per death averted is lower when compared to the long course regimens. Quality control of drugs and more funding for the programme are important urgent requirements.

Supervision of anti-TB treatment has been recognized as an important aspect of TB control and the performance of DOTS strategy under RNTCP that is being expanded in a phased manner has been encouraging. DOTS minimizes deaths due to TB and averts hospitalization. In India it has been estimated that for every 1% of GDP spent on DOTS, there would be a return of 8% per annum. Analysis of TB control programmes in some African countries has shown that treating smear positive TB costs around 20-57 dollars per death averted and the cost per discounted year of life saved is less than 10 US dollars. Hence, there are very few interventions that are as cost effective as anti-TB treatment. Therefore, TB control interventions must be intensified considering the enormous burden imposed by TB both in terms of suffering and the socio - economic impact on our country. Since TB control activities are also one of the most cost effective interventions, appropriate actions aimed at reducing the enormous burden of TB must be accorded the highest priority. For this, strong political will and advocacy are required to highlight enormity of the problem due to TB for allocation of appropriate budget for TB control programmes.

Key Words: *Health Economics; Constraints; SCC; DOTS; Financial Support.*

Total: 3

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077: PUTTING THE KNOWLEDGE TO ACTION AT THE NATIONAL TUBERCULOSIS INSTITUTE, BANGALORE

Sudha S Murthy: NTI Bulletin 1995, 31, 14-17.

Knowledge knows no bounds. In today's world there is a glut of information. From this vast amount of information, the pertinent and relevant knowledge has to be selected. In the words of Rene Dubos practical application of knowledge is to think globally and act locally. The objective of this paper is to enumerate the efforts made and action taken at the NTI Library, Bangalore to repackage the information and knowledge for practical use. NTI was established in 1959 by the GOI to evolve control strategies for TB; train man power for this purpose; carry out operational field research and to monitor the functioning of the programme at the national level.

The NTI as *INFORMATION PRODUCER* through research studies has contributed towards TB control in developing countries. Applied and operational research have dealt with practical application and managerial decision making. The findings of these studies have been widely disseminated through various publications. This information has been classified as Applied research, Conceptual, Programme information, Popular and Elementary. Programme manuals, Technical reports and information in the form of audio visual aids have also been brought out. The NTI Library as an *INFORMATION PROVIDER* has strived hard to meet these information needs. The role of the librarian has been pivotal for technical documentations, coordination of publications and dissemination of information. Users and visitors to the library are given guidelines on the nature of documents available and how to use various catalogues and indexes.

The vision for the future '2001' envisages for NTI as *INFORMATION PRODUCER* on TB surveillance, estimating Annual risk of infection and training trainers of

the TB control programme. The NTI Library as *INFORMATION PROVIDER* will be oriented to produce specific brief reports, more visual than didactic. The entry of electronic media is bound to bring about changes in the data retrieval process. It may not be possible to render these services in future without pricing them.

Key words: *NTI; Information Producer; Information Provider.*

078 : DIGITIZATION: A PRACTICAL EXPERIENCE AT THE A NATIONAL TUBERCULOSIS INSTITUTE, BANGALORE

Sudha S Murthy: Information Studies 2005,11,109-125

The objective of digitization is principally to create content of databases to facilitate access to, preservation and dissemination of information resources. This paper is based on the experience of digitization at the NTI, Bangalore, a WHO-sponsored collaborative project: "Health InterNetwork India" Tuberculosis -India. The various aspects of conceptualization of the digitization project, measurement criteria for inputs and outputs, the ability to access and retrieve information are discussed in detail. An important dimension of digitization process is co-ordination between information technology expert and library professionals. The standards and guidelines followed and problems encountered are mentioned. The importance of securing consent for archiving and sharing resources globally from the concerned parties is pointed out. Efforts made in use digital library software operable in a network environment and the importance of meta data and vocabulary management tools in accessing, searching and retrieving; digitized documents are highlighted.

Key words: Digitization, NTI, WHO, Health InterNetwork India

Total: 2

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